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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

FOR ACTION

Item 1 – AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs
Board Sponsored Bill
Committee Recommendation: Support

Summary: The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard.

A copy of the bill and committee analysis is in Attachment 1.

Item 2 – SB 1111 (B&P Committee) Omnibus Bill
Committee Recommendation: Support

Summary: This is a committee omnibus bill that includes eight changes the board is proposing for the Business and Professions Code. These change are:

1. Rules of Professional Conduct: B&P 4005 & 4206
2. Recast and Revision: Requirements For Designated Representatives: B&P 4053
3. Technical Updates to Licensing Provisions: B&P 4127.5, 4205 & 4400
4. Continuing Education Requirements: B&P 4231 & 4232
5. Pharmacist Recovery Program: B&P 4360-4373
6. Pharmacy Technician Program: B&P 4023.5, 4038, 4114, 4115, 4115.5 & 4202
7. Letter of Admonishment: B&P 4315
8. Impairment or Theft by Licensed Individuals: B&P 4104

These changes cover are being proposed to clean up previous legislation, update the law or respond to state and national trends in regulating pharmacies and pharmacists. All the proposals are non-controversial. They have been reviewed and discussed at least twice during a public meeting of the board, and have been approved by the board for sponsorship.

A copy of the bill is in Attachment 2.

Item 3 – AB 497 (Negrete McLeod) Drug Wholesalers and Manufacturers: Licensure Exemption
Committee Recommendation: Oppose

Summary: This bill would exempt from the licensing requirements of B&P 4161, a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices into this state solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For the purposes of the bill, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity. This bill reverses provisions enacted in last year in board sponsored bill AB 2628 (Chapter 887, Statutes of 2004).

A copy of the bill, the board's analysis, and committee analysis are in Attachment 3.

Item 4 – SB 734 (Torlakson) Controlled Substances
Committee Recommendation: Oppose Unless Amended

Summary: The bill is sponsored the Department of Justice. The author's intent is to make clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement.

Amendments: 1) Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ. 2) Delete the requirement that the privileges of a practitioner to prescribe controlled substances be printed on the prescription form. (Page 10, lines 10-19). 3) Delete the requirement that a pharmacist must report to the DOJ the method of payment used by a customer when purchasing Schedule II and III drugs. (Page 13, line 5).

A copy of the bill, the board's analysis, and committee analysis are in Attachment 4.

Item 5 – Right to Refuse to Fill a Prescription
Committee Recommendation:

AB 21 (Levine) Pharmacists: Prescriptions, would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she has notified his or her employer in writing. The bill would make a violation of its provisions unprofessional conduct, subject to disciplinary action by the board. (B&P 4069)

SB 644 (Ortiz) Dispensing Prescription Drugs And Devices, would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. (B& P 733)

A copy of the bill, the board's analysis, and committee analysis are in Attachment 5.

Item 6 – Pseudoephedrine
Committee Recommendation: Oppose SB 152

AB 283 (Koretz) Pseudoephedrine: Retail Sale, would limit access to ephedrine and pseudoephedrine products by requiring 1) the products be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the DOJ. AB 283 would place these provisions in H&SC 11100.01.

SB 152 (Speier) Pseudoephedrine, would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1.

A copy of the bill and the board's analysis are in Attachment 6.

Item 7 – AB 446 (NEGRETE MCLEOD) Settlement Agreements (Gag Clauses)
Note: The board supported similar legislation, AB 320, in 2003.
Committee Recommendation: Support

Summary: This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator.

A copy of the bill and the board's analysis are in Attachment 7.

Item 8- SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services
Note: Board supported similar legislation, SB 393, in 2003.
Committee Recommendation: Support

Summary: Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes.

A copy of the bill and the board's analysis are in Attachment 8.

Item 9 – AB 896 (Matthews) Clinical laboratories
Notes: Author has dropped AB 1370, a duplicate bill to AB 896.
The board supported similar legislation, AB 1460, in 2003.
Committee Recommendation: Support

Summary: This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

A copy of the bill and the board's analysis are in Attachment 9.

Item 10 – AB 657 (Karnette) Pharmacies: Prescription Containers: Labels
Note: Similar legislation, AB 288 (Mountjoy), has been dropped by the author.
Committee Recommendation:

Summary: Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription, unless the patient, physician, or a parent or legal guardian of a minor patient requests that the information be omitted.

A copy of the bill and the board's analysis are in Attachment 10.

Item 11 – AB 225 (Negrete McLeod) Electronic Prescription Information
Committee Recommendation: Support if Amended

Summary: This bill allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances.

Amendment: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient's choice.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 11.

Item 12 – AB 522 (Plescia) Automated drug delivery system
Committee Recommendation: Support if Amended

Summary: This bill is intended to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

Amendment: Add the words "and dosage" to page 3, line 37 to read:

"After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

A copy of the bill, the board's analysis, and committee analysis are in Attachment 12.

Item 13 – SB 401 (Ortiz) Medical information: Pharmacies: Marketing
Committee Recommendation:

Summary: This bill would define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs.

A copy of the bill, the board's analysis, and committee analysis are in Attachment 13.

Item 14 – Other Bills for Consideration

Note: The committee recommended No Position on the remaining bills, but would like staff to watch for amendments.

A copy of the bill, the board's analysis, and committee analysis (if available) are in Attachment 14.

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of California Drug Safety

Summary: This bill would establish the California Drug Safety Watch, which would require the construction of a public database of adverse prescription drug reactions

SB 380 (Alquist) Drugs: Adverse Event Reporting

Summary: This bill would require a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

AB 72 (Frommer) Clinical Trials

Summary: This bill would require pharmaceutical companies to submit to the state the results of all studies on the safety and efficacy of prescription drugs sold in California

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AB 73 (Frommer) Prescription Drugs: Importation: Procurement

Summary: This bill would establish a state Web site to help patients purchase lower-cost prescription drugs from pharmacies in Canada, Britain and Ireland.

AB 74 (Gordon) California Rx Prescription Drug Hotline

Summary: This bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs

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SB 19 (Ortiz) California Rx Program

Summary: This bill is sponsored by the Governor and would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

AB 75 (Frommer) Pharmaceutical Assistance Program

Summary: This bill would establish a prescription drug discount program for low-income state residents

AB 76 (Frommer) Office of Pharmaceutical Purchasing

Summary: This bill would place the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

AB 306 (Baca) Purchasing Pool for Prescription Drugs

Summary: This bill would establish a prescription drug purchasing pool that would allow employer health plans and the uninsured to join with state and local governments in the purchase of prescription drugs.

AB 78 (Pavley) Pharmacy Benefits Management

Summary: The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues.

SB 798 (Simitian) Prescription Drugs: Collection And Distribution Program

Summary: This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Attachment 1

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AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend ~~Sections 4037 and~~ *Section* 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

~~The~~

Existing law, the Pharmacy Law, provides for the licensing and regulation *by the California State Board of Pharmacy* of pharmacists, *pharmacies,* and ~~associated persons by the California State Board of Pharmacy. A~~ *other related practices and makes a* violation of ~~the~~ *that* law ~~is~~ a crime. *The Pharmacy Law defines various terms for its purposes, including "manufacturer".*

This bill would *delete the definition of manufacturer. The bill would* define compounding of a prescription drug for the purposes of ~~that law~~ *the Pharmacy Law* and would make other related changes in that regard. Because ~~this~~ *the* bill would ~~revise the definition of a crime~~ *specify requirements for compounded drug products under the Pharmacy Law*, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form, flavor, or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal, or topical administration.

SEC. 2. Section 4033 of the Business and Professions Code is repealed.

~~SEC. 3. Section 4037 of the Business and Professions Code is amended to read:~~

~~4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where dangerous drugs and dangerous devices are stored. "Pharmacy" includes, but is not limited to, any area, place, or premises licensed by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, derived, compounded, repackaged, furnished, sold, or dispensed at retail.~~

~~(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.~~

~~SEC. 4.~~

SEC. 3. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

~~SEC. 5.~~

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

~~SEC. 6.~~

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~SEC. 7.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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BILL ANALYSIS
AB 595

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Gloria Negrete McLeod, Chair
AB 595 (Negrete McLeod) - As Amended: March 29, 2005

SUBJECT : Pharmacy: compounding of prescription drugs.

SUMMARY : Defines the term "compounding" and makes other related changes for the purposes of identifying, developing standards for, and regulating the combination or alteration of drugs within a licensed pharmacy. Specifically, this bill :

1)Defines the term "compounding" to mean any of the following activities within a pharmacy:

a) Altering the dosage, form, flavor, or delivery system of a drug;

b) Combining components or active ingredients; and,

c) Preparing a drug product from bulk chemicals.

2)Excludes from the definition of "compounding" those drugs that are reconstituted pursuant to the manufacturer's direction for oral, rectal, or topical administration.

3)Allows drug compounding under the following conditions:

a) The compounded drug will be dispensed pursuant to a prescription.

b) The compounded drug will be dispensed to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

c) The anticipatory compounding of drugs may be performed for limited quantities, as defined in regulations to be adopted by the California Board of Pharmacy (Board), where the quantity is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients. However, a pharmacy that compounds drugs under a contract with another pharmacy may not conduct anticipatory drug compounding.

e) The repackaging of a previously dispensed drug may be performed at the request of the patient or the patient's agent.

EXISTING LAW provides the Board of Pharmacy with regulatory authority over anyone who handles or prepares a dangerous drug for sale in California.

Existing law provides the state Department of Health Services (DHS) with regulatory authority over any person who manufactures a drug. This authority includes compounding, repackaging and relabeling.

Existing federal law, the Food Drug and Cosmetic Act (FDCA), establishes federal regulatory authority over the manufacture of drugs.

FISCAL EFFECT : Unknown

COMMENTS :

Purpose of this bill . According to the author's office, "Compounding by pharmacies is a practice that is centuries old. In the 1950s, with the rise in large drug manufacturers, the practice began to decline. With the need for specialized drugs to treat ailments that do not affect the public at large, and are therefore not profitable for large-scale manufacturers to produce, there has been a resurgence in compounding drugs by pharmacies. It is estimated that compounding may make up one percent of the prescriptions filled. With the increase in compounding have come news reports of people dying from improperly compounded drugs. Since 1990 the FDA is aware of 200 adverse drug events involving 71 compounded drugs that resulted in thirteen hospitalizations and three deaths.

"Given the increase in compounding activity and potential harm to the public from improperly compounded drugs, it is important that the board establish standards for those pharmacies that compound to protect the public health."

Support . The sponsor of this bill, the California State Board of Pharmacy, states: "Over the last ten years there has been an increase in compounding by pharmacies. While federal and state food and drug laws, as well as California's Pharmacy Law, recognize compounding as a proper function of pharmacy practice, currently there are no basic standards that pharmacies must follow when compounding drugs. Given the increase in compounding activity and potential harm to the public from improperly compounded drugs, it is important that the board establish standards for those pharmacies that compound to

protect the public health. AB 595 would create these standards.

"The provisions in this measure were developed over a one-year period in a series of meetings with the pharmacies that compound."

Protecting consumers and businesses by eliminating regulatory overlap . Currently, drug compounding is subject to regulation by the federal Food and Drug Administration (FDA) and the state Department of Health Services because compounding is considered drug "manufacturing" and subject to further regulation by the Board of Pharmacy because it is a drug being handled by a pharmacy for purposes of sale in California. In 1997, Congress attempted to clarify the extent of their authority by exempting drug compounding from the federal Food Drug and Cosmetic Act. For reasons unrelated to the exemption, the entire law, including the drug compounding exemption, was struck down by the Supreme Court in 2002. In response to the Court's decision, FDA issued a compliance policy guide that attempts to provide the drug compounding industry with a sense of when it believes drug compounding is more analogous to drug manufacturing and thus subject to an enforcement action. Unfortunately, current statute continues the regulatory ambiguity, uncertainty, and overlap between federal and state government entities.

It is unknown when and if Congress will once again pursue enactment of legislation to exempt drug compounding from FDCA. However, the practical effect of the FDA's compliance policy guide was to delegate to states the authority to regulate drug compounding when it is done to meet the unique needs of individual patients. AB 595 was developed as a collaborative effort that included practicing pharmacists, FDA, and DHS, and incorporates both of the principles of FDA's compliance policy guide into state law. This will protect consumers because it

gives the Board of Pharmacy clear direction, authority and standards for the regulation of drug compounding within pharmacies. Further, the bill will provide pharmacies with clear standards that will, if followed, eliminate the state's statutory and regulatory overlap between the Board and DHS. Presumably, this bill will, when coupled with FDA's current compliance policy guidelines, eliminate the regulatory overlap between the state and the federal FDA.

Previous legislation . SB 293 (Torlakson), Chapter 827, Statutes of 2001, requires pharmacies that compound injectable sterile drug products to obtain a special license from the Board. This is a highly specialized area of pharmacy practice that is now closely regulated. The Board is required to annually inspect these pharmacies to assure that the pharmacy is in compliance with the regulations on sterile compounding.

REGISTERED SUPPORT / OPPOSITION :

Support

California State Board of Pharmacy (sponsor)
Costa Mesa Pharmacy

Opposition

None on file.

Analysis Prepared by : Ross Warren / B. & P. / (916) 319-3301

Attachment 2

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SENATE BILL No. 1111

Introduced by Committee on Business, Professions and Economic Development (Senators Figueroa (Chair), Aanestad, Campbell, Florez, Morrow, Murray, and Simitian)

March 30, 2005

An act to amend Sections 2053.6, 2230, 2234.1, 2741, 2760.1, 3735, 3739, 4005, 4038, 4053, 4104, 4114, 4115, 4115.5, 4127.5, 4202, 4205, 4231, 4232, 4315, 4360, 4364, 4365, 4366, 4369, 4371, 4372, 4373, 4400, and 4850 of, to add Sections 3779 and 4023.5 to, to repeal Sections 3735.3, 3736, 3775.2, 3775.3, 4206, 4363, 4367, 4368, and 4370 of, and to repeal and add Sections 4361 and 4362 of, the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1111, as introduced, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the regulation of various professions, including physicians and surgeons, nurses, respiratory care practitioners, and pharmacists.

This bill would revise and recast certain provisions regulating these professions. The bill would require the Division of Medical Quality to organize itself as 2 panels of 7 members. The bill would require an applicant for a license to practice respiratory care to successfully pass the national respiratory therapist examination. The bill would require a pharmacy to have written policies and procedures for detecting chemical, mental, or physical impairment among licensed individuals employed by or with the pharmacy. The bill would require a pharmacy to report certain information to the California State Board of Pharmacy for the protection of the public. The bill would require the board to operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competence may be

impaired due to abuse of alcohol, drug use, or mental illness. The bill would establish requirements for this program and require the board to contract with one or more qualified contractors to administer the program. Because the bill would increase fees under the Pharmacy Law that would be deposited into the Pharmacy Board Contingent Fund which is continuously appropriated, the bill would make an appropriation.

Because a violation of the bill with respect to pharmacists would be a crime, it would impose a state-mandated local program

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 2053.6 of the Business and Professions Code is amended to read:

2053.6. (a) A person who provides services pursuant to Section 2053.5 that are not unlawful under Section 2051~~, 2052, or 2053~~ *or 2052* shall, prior to providing those services, do the following:

(1) Disclose to the client in a written statement using plain language the following information:

(A) That he or she is not a licensed physician.

(B) That the treatment is alternative or complementary to healing arts services licensed by the state.

(C) That the services to be provided are not licensed by the state.

(D) The nature of the services to be provided.

(E) The theory of treatment upon which the services are based.

(F) His or her educational, training, experience, and other qualifications regarding the services to be provided.

(2) Obtain a written acknowledgement from the client stating that he or she has been provided with the information described in paragraph (1). The client shall be provided with a copy of the

written acknowledgement, which shall be maintained by the person providing the service for three years.

(b) The information required by subdivision (a) shall be provided in a language that the client understands.

(c) Nothing in this section or in Section 2053.5 shall be construed to do the following:

(1) Affect the scope of practice of licensed physicians and surgeons.

(2) Limit the right of any person to seek relief for negligence or any other civil remedy against a person providing services subject to the requirements of this section.

SEC. 2. Section 2230 of the Business and Professions Code is amended to read:

2230. (a) All proceedings against a licensee for unprofessional conduct, or against an applicant for licensure for unprofessional conduct or cause, shall be conducted in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) except as provided in this chapter, and shall be prosecuted by the Senior Assistant Attorney General of the Health Quality Enforcement Section.

(b) For the purpose of exercising its disciplinary authority against a physician and surgeon pursuant to this chapter and the Administrative Procedure Act, the Division of Medical Quality shall organize itself as two panels of ~~six~~ *seven* members. Two members of each panel shall be public members. For purposes of this article, "agency itself," as used in the Administrative Procedure Act, means a panel of the division as described in this subdivision. The decision or order of a panel imposing any disciplinary action pursuant to this chapter and the Administrative Procedure Act shall be final.

SEC. 3. Section 2234.1 of the Business and Professions Code is amended to read:

2234.1. (a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine if that treatment or advice meets all of the following requirements:

(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine he or she practices.

(3) It does not cause a delay in~~,~~ or discourage traditional diagnosis of~~,~~ a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine" means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

SEC. 4. Section 2741 of the Business and Professions Code is amended to read:

2741. ~~Notwithstanding Section 135, an applicant who fails to pass the examination may be reexamined within that period of time as the board, by regulation, deems appropriate, but not more frequently than once every three months.~~ An application for reexamination shall be accompanied by the fees prescribed by this chapter.

SEC. 5. Section 2760.1 of the Business and Professions Code is amended to read:

2760.1. (a) A registered nurse whose license has been revoked, or suspended or who has been placed on probation may petition the board for reinstatement or modification of penalty, including reduction or termination of probation, after a period not less than the following minimum periods has elapsed from the effective date of the decision ordering that disciplinary action, or if the order of the board or any portion of it is stayed by the board itself or by the superior court, from the date the disciplinary action is actually implemented in its entirety:

(1) Except as otherwise provided in this section, at least ~~three~~ *two* years for reinstatement of a license that was revoked, except that the board may, in its sole discretion, specify in its order a

lesser period of time provided that the period shall be not less than one year.

(2) At least two years for early termination of a probation period of three years or more.

(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

(b) The board shall give notice to the Attorney General of the filing of the petition. The petitioner and the Attorney General shall be given timely notice by letter of the time and place of the hearing on the petition, and an opportunity to present both oral and documentary evidence and argument to the board. The petitioner shall at all times have the burden of proof to establish by clear and convincing evidence that he or she is entitled to the relief sought in the petition.

(c) The hearing may be continued from time to time as the board deems appropriate.

(d) The board itself shall hear the petition and the administrative law judge shall prepare a written decision setting forth the reasons supporting the decision.

(e) The board may grant or deny the petition, or may impose any terms and conditions that it reasonably deems appropriate as a condition of reinstatement or reduction of penalty.

(f) The petitioner shall provide a current set of fingerprints accompanied by the necessary fingerprinting fee.

(g) No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole, or subject to an order of registration pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.

(h) Except in those cases where the petitioner has been disciplined for violation of Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.

SEC. 6. Section 3735 of the Business and Professions Code is amended to read:

3735. Except as otherwise provided in this chapter, no ~~person~~ *applicant* shall receive a license under this chapter without first successfully passing ~~an examination given under the direction of the board. The examination shall be in writing and shall be conducted under the regulations prescribed by the board~~ *the national respiratory therapist examination conducted by those persons, and in the manner and under the rules and regulations, as the board may prescribe.*

SEC. 7. Section 3735.3 of the Business and Professions Code is repealed.

~~3735.3. An applicant for a license as a respiratory care practitioner may not be scheduled to sit for the examination until verification from the program director, in a form acceptable to the board, declaring that the applicant has completed his or her respiratory training program and has met all the educational requirements for the awarding of an associate degree is received in the board's office. An official transcript from the educational institution's registrar's office shall be submitted to the board prior to the issuance of a license as a respiratory care practitioner.~~

SEC. 8. Section 3736 of the Business and Professions Code is repealed.

~~3736. Examinations for a license as a respiratory care practitioner may be conducted by the board under a uniform examination system, and for that purpose the board may make any arrangements with organizations furnishing examination material as may in its discretion be desirable.~~

SEC. 9. Section 3739 of the Business and Professions Code is amended to read:

3739. (a) (1) Except as otherwise provided in this section, every ~~graduate of an approved respiratory care program who has filed an initial respiratory care practitioner application~~ *person who has filed an application for licensure* with the board may, between the dates specified by the board, perform as a respiratory care practitioner applicant under the direct supervision of a respiratory care practitioner licensed in this state *provided he or she has met education requirements for licensure as may be certified by his or her respiratory care program, and if ever attempted, has passed the national respiratory therapist examination.*

(2) During this period the applicant shall identify himself or herself only as a "respiratory care practitioner applicant."

(3) If for any reason the license is not issued, all privileges under this subdivision shall automatically cease on the date specified by the board.

(b) If an applicant fails ~~to take the next available examination without good cause or fails to pass the examination and receive a license~~ *the national respiratory therapist examination*, all privileges under this section shall automatically cease on the date specified by the board.

~~(c) Notwithstanding subdivision (a), an applicant for licensure who was previously licensed by the board, but who allowed his or her license to expire for more than three years, shall be allowed to practice as a respiratory care practitioner applicant under the direct supervision of a respiratory care practitioner licensed in this state between the dates specified by the board. During this period, the applicant shall identify himself or herself only as a "respiratory care practitioner applicant." If for any reason the license is not issued, all privileges under this subdivision shall cease on the date specified by the board.~~

~~(d)~~

(c) No applicant for a respiratory care practitioner license shall be authorized to perform as a respiratory care practitioner applicant if cause exists to deny the license.

(d) "Under the direct supervision" means assigned to a respiratory care practitioner who is on duty and immediately available in the assigned patient care area.

SEC. 10. Section 3775.2 of the Business and Professions Code is repealed.

~~3775.2. (a) The fee for approval of providers of continuing education shall be established by the board at not more than the following:~~

~~(1) The initial application approval fee shall not exceed seven hundred dollars ($700).~~

~~(2) The annual renewal fee shall not exceed three hundred fifty dollars ($350).~~

~~(3) The fee for rereview or additional approval of any amendments to existing providers shall not exceed three hundred fifty dollars ($350).~~

~~(b) The delinquency fee for the annual renewal fee shall be 50 percent of the annual renewal fee.~~

SEC. 11. Section 3775.3 of the Business and Professions Code is repealed.

~~3775.3. The Respiratory Care Board of California shall report to the appropriate policy and fiscal committee of each house of the Legislature whenever the Respiratory Care Board of California proposes or adopts an increase in any fee, and shall specify the rationale and justification for that increase.~~

SEC. 12. Section 3779 is added to the Business and Professions Code, to read:

3779. For purposes of license verification, a person may rely upon a printout from the board's Internet Web site that includes the issuance and expiration dates of any license issued by the board.

SEC. 13. Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; pertaining to the sale of drugs by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

~~(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.~~

~~(d)~~

(c) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 14. Section 4023.5 is added to the Business and Professions Code, to read:

4023.5. For the purposes of this chapter "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

SEC. 15. Section 4038 of the Business and Professions Code is amended to read:

4038. *(a)* "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.

SEC. 16. Section 4053 of the Business and Professions Code, as added by Section 7 of Chapter 857 of the Statutes of 2004, is amended to read:

4053. (a) ~~Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a designated representative to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410)~~ *Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the*

handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) ~~This section shall become operative on January 1, 2006~~ *Section 4051 shall not apply to any laboratory licensed under*

Section 351 of Title III of the Public Health Service Act (Public Law 78–410).

SEC. 17. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) ~~Pharmacies~~ *Every pharmacy* shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is *discovered or* known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, *or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.*

(b) ~~Pharmacies shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy~~ *Every pharmacy shall have written policies and procedures for detecting chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.*

(c) ~~The board may, by regulation, establish requirements for reporting to the board conduct or incidents described in subdivision (a) or (b)~~ *Every pharmacy shall report to the board, within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy:*

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(7) Any information supporting a reasonable suspicion that a licensed individual is chemically, mentally, or physically impaired to the extent it affects his or her ability to practice.

(8) Any information supporting a reasonable suspicion that a licensed individual has engaged in theft, diversion, or self-use of dangerous drugs.

(d) Anyone participating in good faith in the making of a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

SEC. 18. Section 4114 of the Business and Professions Code is amended to read:

4114. (a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the *direct* supervision *and control* of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

SEC. 19. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) ~~Notwithstanding any other provision of law, a~~ *A* pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of~~,~~ a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty~~, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist~~.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the ~~direct~~ supervision ~~and control~~ of a pharmacist. Any pharmacy that employs a pharmacy technician ~~to perform tasks specified in subdivision (a)~~ shall do so in conformity with the regulations adopted by the board ~~pursuant to this subdivision~~.

(e) ~~(1)~~ No person shall act as a pharmacy technician without first being ~~registered with~~ *licensed by* the board as a pharmacy technician ~~as set forth in Section 4202~~.

~~(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.~~

~~(f) (1) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.~~

~~(2) This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician~~

~~to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.~~

~~(g)~~

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not

to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

~~(h)~~

(g) Notwithstanding subdivisions *(a) and* (b) ~~and (f)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision ~~(g)~~ *(f)*.

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

SEC. 20. Section 4115.5 of the Business and Professions Code is amended to read:

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician ~~student~~ *trainee* may be placed in a pharmacy ~~as a pharmacy technician trainee~~ to complete an externship for the purpose of obtaining practical training ~~that is required by the board as a condition of becoming registered as a pharmacy technician. A "pharmacy technician student" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education~~ *required to become licensed as a pharmacy technician.*

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the

~~immediate, personal~~ *direct* supervision and control of a pharmacist. ~~A pharmacist supervising a pharmacy technician trainee shall be on the premises and have the trainee within his or her view at any time the trainee performs the duties described in subdivision (a) of Section 4115.~~

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient *or by engaging in other verification procedures that are specifically approved by board regulations*.

(4) ~~No more than one pharmacy technician trainee per pharmacist may participate in an externship as described in subdivision (a) under the immediate, personal supervision and control of that pharmacist at any time the trainee is present in the pharmacy~~ *A pharmacist may only supervise one pharmacy technician trainee at any given time.*

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community

pharmacy setting or in a single department in a hospital pharmacy.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her ~~student~~ *trainee* status.

SEC. 21. Section 4127.5 of the Business and Professions Code is amended to read:

4127.5. The fee for the issuance of a *nongovernmental* license, or renewal of a license, to compound sterile drug products shall be five hundred dollars ($500) and may be increased to six hundred dollars ($600).

SEC. 22. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) ~~An applicant for registration as a pharmacy technician shall be issued a certificate of registration~~ *The board may issue a pharmacy technician license to an individual* if he or she is a high school graduate or possesses a ~~general education development~~ *General Education Development* equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy ~~accredited by the American Council on Pharmaceutical Education or a school of pharmacy~~ recognized by the board. Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician ~~certificate of registration~~ *license* must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the ~~registration~~ *licensure* of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of

subdivision (a). Proof of the qualifications of any applicant for ~~registration~~ *licensure* as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of ~~registration~~ *licensure*, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a ~~registration~~ *license* issued pursuant to this section on any ground specified in Section 4301.

SEC. 23. Section 4205 of the Business and Professions Code is amended to read:

4205. (a) A license issued pursuant to Section 4110, 4120, ~~4130,~~ 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for ~~use for animals and poultry~~ *animal use*.

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of ~~this article~~ *Article 9 (commencing with Section 4140) of this chapter*.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

SEC. 24. Section 4206 of the Business and Professions Code is repealed.

~~4206. The rules of professional conduct adopted by the board shall be printed as a part of the application for licenses and every applicant shall subscribe thereto when making an application.~~

SEC. 25. Section 4231 of the Business and Professions Code is amended to read:

4231. *(a)* The board shall not ~~issue any renewal certificate~~ *renew a pharmacist license* unless the applicant submits proof satisfactory to the board that he or she has successfully completed *30 hours of* approved courses of continuing ~~pharmaceutical~~ *pharmacy* education during the two years preceding the application for renewal. ~~The continuing education required by this article shall consist of the number of clock hours, not to exceed 30 clock hours, designated by regulation adopted by the board. This section shall not apply to licensees during the first two years immediately following their graduation from a college of pharmacy or department of pharmacy of a university recognized by the board.~~

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704.

SEC. 26. Section 4232 of the Business and Professions Code is amended to read:

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional ~~pharmaceutical~~ *pharmacy* education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology,

and any other subject matter as represented in curricula of accredited colleges of pharmacy.

SEC. 27. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the

board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available ~~on the pharmacy premises~~ a copy of the letter of admonishment and corrective action plan, *if any,* for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

SEC. 28. Section 4360 of the Business and Professions Code is amended to read:

4360. ~~It is the intent of the Legislature that the board seek ways and means to identify and~~ *The board shall operate a pharmacists recovery program to* rehabilitate pharmacists *and intern pharmacists* whose competency may be impaired due to abuse of alcohol ~~and other drugs, or due to mental illness, so that these pharmacists may be treated and returned~~, *drug use, or mental illness. The intent of the pharmacists recovery program is*

to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety. ~~It is also the intent of the Legislature that the board shall implement this legislation by establishing a diversion program as a voluntary alternative to traditional disciplinary actions.~~

SEC. 29. Section 4361 of the Business and Professions Code is repealed.

~~4361. As used in this article:~~

~~(a) "Diversion program" means a rehabilitation program designed and administered by a contracting Employee Assistance Program, available to the board in conjunction with, or as an alternative to, other traditional sanctions that the board may impose upon pharmacists pursuant to disciplinary actions within its jurisdiction.~~

~~(b) "Employee assistance program" means an agency or organization that provides confidential assessments and referral services for persons experiencing problems related to alcohol, drug abuse, or mental illness.~~

~~(c) "Pharmacists recovery program" or "program" means the rehabilitation program created by this article for pharmacists whose competency may be threatened or diminished due to abuse of alcohol or other drugs.~~

~~(d) "Volunteer intervenor" means a pharmacist recruited through a pharmacists' professional association who is available and trained to assist pharmacists seeking the benefits of the pharmacist's recovery program.~~

SEC. 30. Section 4361 is added to the Business and Professions Code, to read:

4361. (a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.

(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.

SEC. 31. Section 4362 of the Business and Professions Code is repealed.

~~4362. The program shall fulfill two distinct functions. It shall serve as a diversion program to which the board may refer licentiates, where appropriate, instead of, or in addition to, other means of disciplinary action, and it shall be a confidential source~~

~~of treatment for pharmacists who, on a strictly voluntary basis and without the knowledge of the board, desire to avail themselves of its services.~~

SEC. 32. Section 4362 is added to the Business and Professions Code, to read:

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

(1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.

(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on the pharmacists or intern pharmacists entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

SEC. 33. Section 4363 of the Business and Professions Code is repealed.

~~4363. The board shall administer this article, provided that the names and all identifying information pertaining to those pharmacists who voluntarily seek the services of the program, apart from the institution of any disciplinary action of the board, shall not be disclosed to the board, except as provided in Sections 4370 and 4371.~~

SEC. 34. Section 4364 of the Business and Professions Code is amended to read:

4364. *(a)* The board shall establish criteria for the participation of pharmacists *and intern pharmacists* in the *pharmacists* recovery program.

(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.

(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 35. Section 4365 of the Business and Professions Code is amended to read:

4365. The board shall contract with one or more ~~employee assistance programs to administer the pharmacists recovery program statewide. The contractor shall be selected through a competitive bid process, and the contract may be renewed annually~~ *qualified contractors to administer the pharmacists recovery program.*

SEC. 36. Section 4366 of the Business and Professions Code is amended to read:

4366. The functions of the ~~employee assistance~~ *contractor administering the pharmacists recovery* program shall include, *but not be limited to,* the following:

(a) To evaluate those pharmacists *and intern pharmacists* who request participation in the program ~~according to the guidelines prescribed by the board~~.

(b) To ~~review and designate those treatment facilities and services to which pharmacists in the program may be referred~~ *develop a treatment contract with each participant in the pharmacists recovery program.*

(c) To ~~receive and review information concerning a pharmacist's participation in the program~~ *monitor the compliance of each participant with their treatment contract.*

~~(d) To assist pharmacists' professional associations in publicizing the program.~~

~~(e)~~

(d) To prepare reports ~~to be submitted to~~ *as required by* the board.

(e) To inform each participant of the procedures followed in the program.

(f) To inform each participant of their rights and responsibilities in the program.

(g) To inform each participant of the possible consequences of noncompliance with the program.

SEC. 37. Section 4367 of the Business and Professions Code is repealed.

~~4367. The board shall designate a program coordinator whose responsibilities shall include the following:~~

~~(a) To serve as liaison between the board and the employee assistance program.~~

~~(b) To monitor and evaluate the employee assistance program.~~

~~(c) To assist the board enforcement unit in tracking pharmacists referred to the program as part of, or alternative to, disciplinary proceedings.~~

SEC. 38. Section 4368 of the Business and Professions Code is repealed.

~~4368. The board shall contract with a pharmacists' professional association with statewide representation for the following purposes:~~

~~(a) To coordinate the voluntary participation in the program.~~

~~(b) To recruit volunteer intervenors and to train them.~~

~~(c) To promote the program within the profession and to the public.~~

~~(d) To establish and maintain a 24-hour statewide toll-free telephone "hotline" service.~~

~~(e) To report to the board on these functions.~~

SEC. 39. Section 4369 of the Business and Professions Code is amended to read:

4369. ~~(a) The board shall inform, in writing, each pharmacist referred to the employees assistance program as part of a board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.~~

~~(b)~~

(a) Any failure to comply with the ~~provisions of the~~ treatment *contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery* program may result in the termination of the pharmacist's *or intern pharmacist's* participation in the ~~diversion~~ *pharmacists recovery* program. The name and license number of a pharmacist *or intern pharmacist* who is terminated ~~for failure to comply with the provisions of the treatment~~ *from the pharmacists recovery* program and the basis for the termination shall be reported to the board.

~~(c)~~

(b) Participation in ~~a~~ *the pharmacists recovery* program ~~under this article~~ shall not be a defense to any disciplinary action that may be taken by the board. ~~Further, no~~

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from ~~a program under this article~~ *the pharmacists recovery program*.

SEC. 40. Section 4370 of the Business and Professions Code is repealed.

~~4370. (a) The employee assistance program shall inform, in writing, each pharmacist who voluntarily participates in the diversion program without referral by the board of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.~~

~~(b) The board shall be informed of the pharmacist's noncompliance with the treatment program if the employee assistance program determines that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public. The board shall be informed of the basis for the pharmacist's termination and of the determination that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public.~~

~~(c) Participation in a program under this article shall not be a defense to any disciplinary action that may be taken by the board. Further, no provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program under this article.~~

SEC. 41. Section 4371 of the Business and Professions Code is amended to read:

4371. The board shall review the ~~activities of the employee assistance~~ *pharmacists recovery* program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the ~~diversion~~ *pharmacists recovery* program. ~~Names of those pharmacists who entered the program voluntarily without the knowledge of the board shall remain confidential from the board except when monitoring by the board reveals misdiagnosis, case mismanagement, or noncompliance by the participant.~~

SEC. 42. Section 4372 of the Business and Professions Code is amended to read:

4372. All board records and records of the ~~employee assistance~~ *pharmacists recovery* program pertaining to the treatment of a pharmacist *or intern pharmacist* in the program shall be kept confidential and are not subject to discovery ~~or~~ , subpoena, *or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code.* However, board records and records of the ~~employee assistance~~ *pharmacists recovery* program may be disclosed and testimony provided in connection with participation ~~pursuant to Section 4369 or 4370~~ *in the pharmacists recovery program*, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist *or intern pharmacist* was terminated from the *pharmacists recovery* program.

SEC. 43. Section 4373 of the Business and Professions Code is amended to read:

4373. No member of the board ~~or the contracting professional association or any volunteer intervenor~~ shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

SEC. 44. Section 4400 of the Business and Professions Code, as added by Section 50 of Chapter 857 of the Statutes of 2004, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a *nongovernmental* wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) *(1)* The fee for application ~~and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars ($100)~~, *investigation, and issuance of a license as a designated representative pursuant to Section 4053 shall be one hundred eighty-five dollars ($185) and may be increased to two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund seventy-five dollars ($75) of the fee.*

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150).

(i) *(1)* The fee for ~~a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55)~~ *the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty dollars ($250). If the applicant is not issued a license as a designated representative, the board shall refund one hundred dollars ($100) of the fee.*

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars ($150).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

~~(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).~~

~~(l)~~

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

~~(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).~~

~~(n)~~

(l) The fee for an intern *pharmacist* license ~~or extension~~ shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

~~(o)~~

(m) The board may~~, by regulation, provide for the waiver~~ *waive* or refund ~~of~~ the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next ~~succeeding~~ regular renewal date.

~~(p)~~

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

~~(q)~~

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

~~(r)~~

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve

in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

~~(s)~~

(q) The fee for any applicant for a *nongovernmental* clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

~~(t)~~

(r) The board shall charge a fee for the processing and issuance of a ~~registration~~ *license* to a pharmacy technician and a separate fee for the biennial renewal of the ~~registration~~ *license.* The ~~registration~~ *license* fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

~~(u)~~

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

~~(v)~~

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

~~(w) This section shall become operative on January 1, 2006.~~

SEC. 45. Section 4850 of the Business and Professions Code is amended to read:

4850. Every person holding a license under this chapter shall conspicuously display ~~a copy of~~ the license in his or her principal place of business.

SEC. 46. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Attachment 3

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AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section 4161 of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as amended, Negrete McLeod. Drug wholesalers and manufacturers: licensure exemption.

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities.

This bill would exempt from this licensure requirement certain ~~intracompany transactions and~~ transactions between affiliated or related ~~companies~~ *wholesalers*, as defined.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4161 of the Business and Professions Code, as added by Chapter 887 of the Statutes of 2004, is amended to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated

representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) The licensure requirements of this section shall not apply ~~to a person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state if that transaction is either of the following:~~

~~(1) An intracompany transaction between the person and a division, subsidiary, or parent of the person.~~

~~(2) A transaction between the person and an affiliated or related company for purposes of stocking or restocking that company. For purposes of this paragraph, an affiliated or related company is one where the person and company are under common ownership and control of the same corporate entity.~~ *to a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For purposes of this subdivision, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.*

(n) This section shall become operative January 1, 2006.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 497 **VERSION: AMENDED APRIL 5, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: NEGRETE MCLEOD**

RECOMMENDED POSITION: OPPOSE

SUBJECT: DRUG WHOLESALERS AND MANUFACTURERS: LICENSURE EXEMPTION.

Existing Law:

Requires a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. (B&P 4161)

This Bill:

Exempts from the licensing requirements of B&P 4161, a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices into this state solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For the purposes of the bill, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.

(B&P 4161 Amended)

Comment:

1) Author's Intent. Last year, the board sponsored AB 2628, which required among other things, that effective January 1, 2005 all wholesaler locations that ship prescription drugs into California had to be licensed with the board as nonresident wholesalers, even if shipping to a California licensed wholesaler. The sponsor believes that the current law is excessive. Given that companies track the movement and transfer of drugs from one facility to another the chances of counterfeited drugs entering the system is remote. Drug wholesalers and distributors support this view.

2) What's at Stake? Protecting the drug supply from the introduction of counterfeit drugs is paramount. No one approach will work on its own, consequently the Food and Drug Administration recommends that states take a multiple prong approach that includes: licensing wholesalers and out of state distributors; establishing a drug pedigree system; and increasing penalties for drug counterfeiters. Last year the Governor signed SB 1307 and AB 2628, which put these measures into effect.

If AB 497 is enacted the board would loose its ability to take enforcement action against unlicensed out of state distributors that ship drugs into California (if the unlicensed distributor is affiliated or related to a wholesaler that is licensed by the board). This loss will weaken the state's ability to protect the safety of the drug supply.

3) Legislative History. In 2004 the board sponsored SB 1307 (Chapter 857, Statutes of 2004) Wholesalers and Manufacturers of Dangerous Drugs and Devices, and AB 2682 (Chapter 887, Statutes of 2004) Pharmacy: Out-of-State Wholesalers.

4) History.

2005

Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 3	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

BILL ANALYSIS
AB 497

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 497 (Negrete McLeod) - As Amended: April 5, 2005

SUBJECT : Drug wholesalers and manufacturers: licensure exemption.

SUMMARY : Exempts from licensure nonresident drug wholesalers that ship, mail or deliver dangerous drugs or dangerous devices solely to an affiliated or related licensed wholesaler. Defines affiliated or related wholesaler as one where the wholesaler shipping, mailing or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.

EXISTING LAW :

1)Establishes the Board of Pharmacy (Board) to regulate and license drug wholesalers, and requires a license to operate as a wholesaler of any dangerous drug or device.

2)Makes operative, effective January 1, 2006 the provisions of #3) through #9) below.

3)Requires a person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state to be considered a nonresident wholesaler.

4)Requires a nonresident wholesaler to be licensed by the Board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

5)Requires a separate license for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state.

6)Requires a nonresident wholesaler to comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the Board.

7)Requires a nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

8)Requires a nonresident wholesaler to at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident.

9)Requires a nonresident wholesaler to identify a designated representative-in-charge who and responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . The author states that this bill addresses the concerns of pharmaceutical distributors by allowing an intracompany transfer of prescription drugs as it relates to the provisions of AB 2682 (Negrete McLeod), Chapter 887, Statutes of 2004, which addressed the second hand market of small "fly-by-night" distributors and a lack of quality regulation. A side effect of this measure was that it placed a significant burden on the three largest pharmaceutical distributors in the nation, Cardinal Health, AmerisourceBergen Corporation and McKesson Corporation, in relation to their automated system of intracompany transfers. These three companies use an automated system to ensure that their 150 distribution centers are never short of a particular product. Because of this automated system, these companies would be in violation of AB 2682, at each facility, unless they are licensed, bonded, and the representative-in-charge is designated, which would cost time and money. The author also points out that a problem might arise because a non-licensed out-of-state distributor might be barred from sending a life-saving drug to a California patient because of a prohibition related to intracompany transfers.

2)WHOLESALE MARKET . In the United States, three major companies account for 90% of wholesale market and buy 95% of their drugs directly from the manufacturer. Secondary wholesalers buy drugs from a range of different sources and tend to serve smaller markets, such as physician offices and specialized markets. In the current system, there are many steps in the distribution chain and drugs are not tracked. Individual pharmacies buy drugs from a wholesaler, but are usually unaware from where that wholesaler received its supply of drugs. This can lead to instances of counterfeiting, such as relabeled or adulterated drugs. Counterfeit cases are few, but one case could affect thousands of patients. For example, in May 2003 the Food and Drug Administration (FDA) issued an alert when nearly 200,000 counterfeit bottles of Lipitor, used

to control cholesterol, made their way onto the market, representing "a potentially significant risk to consumers." There have been several highly publicized cases such as these and the Los Angeles Times, Washington Post, and Wall Street Journal have devoted articles to the wholesale market and how current regulations make it vulnerable to counterfeit drugs.

3)PREVIOUS LEGISLATION . There were two bills last year that dealt with the licensing of nonresident wholesalers. AB 2682 (Negrete McLeod), Chapter 887, Statutes of 2004 enacts a statutory scheme for regulating nonresident wholesalers, which includes a licensure requirement and other requirements listed under "Existing Law" above. SB 1307 (Figueroa), Chapter 857, Statutes of 2004, increases licensing requirements on pharmaceutical wholesalers by establishing bonding requirements, requires all prescription drugs to have a pedigree that tracks the ownership of drugs from the manufacturer to the dispensing pharmacy, and gives the Board of Pharmacy stronger enforcement tools for wholesale violations. The purpose of these bills was to substantially decrease the threat of counterfeit drugs and drug diversion and was designed to address challenges presented by the existing distribution system for prescription drugs.

4)POLICY QUESTION . Does this bill weaken the purposes of AB 2682 and SB 1307? The author of SB 1307 states that these bills were the result of over two years of work by the Board and stakeholders, including pharmacists, health plans, and wholesalers. The process also included public comment. The exemption that is sought in this bill is outside the lengthy process that was involved in developing these bills. In addition, what are the ramifications for the Board and consumers if nonresident wholesalers that are not licensed by the Board introduce adulterated or counterfeit drugs in California's market? SB 1307 also required all prescription drugs to have a "pedigree" that documents the transaction history of the distribution of drugs. Does the justification provided by the sponsor of this bill, which is to save time and money, outweigh the importance of ensuring that adulterated or counterfeit drugs are not introduced into the market? Just on Friday, April 8, 2005, the New York Attorney General announced that AmerisourceBergen, Cardinal and McKesson, the sponsors of this bill, according to the author, were subpoenaed in relation to a probe into the way companies buy drugs from each other. If this bill is adopted, would it undermine the "pedigree" tracking requirements adopted to reduce counterfeit drugs in the market?

5)DOUBLE-REFERRAL . Should this bill pass out of this committee, it would be referred to the Assembly Committee on Business and Professions.

REGISTERED SUPPORT / OPPOSITION :

Support

McKesson Corporation (sponsor)

Opposition

None on file

Analysis Prepared by : Rosielyn Pulmano / HEALTH / (916) 319-2097

Attachment 4

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SENATE BILL No. 734

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as introduced, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by

the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the board or department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the

forms to set forth specified information, as appropriate, with respect to practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and multiple prescribers.

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department.

(7) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11159.2 of the Health and Safety Code is amended to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a ~~Schedule II~~ controlled substance for use by a patient who has a terminal illness shall meet the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate prescription blanks or~~ controlled substance prescription forms in the practitioner's possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order.* Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the

court. Any practitioner possessing prescription ~~blanks~~ *forms* in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender ~~all triplicate prescription blanks or~~ *controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using* controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the ~~Board of Pharmacy~~ *Department of Justice.*

(b) The ~~Board of Pharmacy~~ *department* may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The ~~applicant~~ *department* shall ~~also~~ provide *the applicant with the means and direction to provide* fingerprints *and related information*, in a manner specified by the ~~Board of Pharmacy~~ *department*, for the purpose of completing state ~~and~~, federal, *or foreign* criminal background checks.

(C) *Any applicant described in subdivision (b) shall submit* his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the *department establishes that the* applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision *(l)* of Section 11105 of

the Penal Code. Requests for federal level criminal offender record information *received by the department* pursuant to this section shall be forwarded to the Federal Bureau of Investigation *by the department.*

(D) The department shall assess against each applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits fingerprints and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) ~~Prior to approving a security printer application, the Board of Pharmacy shall submit a copy of the application to the Department of Justice; the Department of Justice may, within 30~~ *The department may, within 60* calendar days of receipt of the application from the ~~Board of Pharmacy~~ *applicant*, deny the security printer application.

(d) The ~~Board of Pharmacy or the Department of Justice~~ *department* may deny a security printer application on any of the following grounds:

(1) The applicant, *any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms,* has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Board of Pharmacy or Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) The ~~Board of Pharmacy~~ *department* shall maintain a list of approved security printers and the ~~Board of Pharmacy~~ *department* shall make this information available to prescribers and other appropriate government agencies, including the ~~Department of Justice~~ *Board of Pharmacy*.

(f) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(g) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(h) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(i) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(j) (1) The ~~Board of Pharmacy or the Department of Justice~~ *department* may revoke its approval of a security printer for a

violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the ~~Board of Pharmacy or the Department of Justice~~ *department* revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

~~(k) Security printer applicants may appeal a denial or revocation by the Board of Pharmacy to the full board in a public meeting of the Board of Pharmacy.~~

SEC. 4. Section 11162.1 of the Health and Safety Code is amended to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall ~~either (A)~~ contain a statement printed on the bottom of the prescription blank that the

~~"Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the~~ "Prescription is void if the number of drugs prescribed is not noted."

(9) *(A)* The preprinted name, category of licensure, license number, ~~and~~ federal controlled substance registration number of the prescribing practitioner.

(B) The privileges of a practitioner to prescribe any of the following controlled substances shall be preprinted beside the prescriber's name and as designated in the prescriber's certificate issued by the federal Drug and Enforcement Agency:

(i) Schedule II narcotic.

(ii) Schedule II nonnarcotic.

(iii) Schedule III narcotic.

(iv) Schedule III nonnarcotic.

(v) Schedule IV.

(vi) Schedule V.

(10) A check box indicating the prescriber's order not to substitute.

(11) An identifying number assigned to the approved security printer by the Department of Justice.

(12) A physician assistant authorized by Section 3502.1 of the Business and Professions Code to issue a drug order may do so under his or her own name on prescription forms preprinted with the information required by Section 11162 that are in compliance with subdivision (d) of Section 3502.1 of the Business and Professions Code.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated

prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) *(A) Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber.*

(B) Each designated prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by the prescriber's name.

(4) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

~~(4)~~

(5) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Date of issue of the prescription.
(8) Date of dispensing of the prescription.
(9) Method of payment for prescription.
(e) This section shall become operative on January 1, 2005.

SEC. 6. Section 11190 of the Health and Safety Code is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.
(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Date of dispensing of the prescription.
(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in ~~either hardcopy or electronic form~~ *a format set by the Department of Justice.*
(d) This section shall become operative on January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 734 **VERSION: INTRODUCED**

AUTHOR: TORLAKSON **SPONSOR: DEPARTMENT OF JUSTICE**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: CONTROLLED SUBSTANCES

Existing Law:

1. Provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2)

2. Provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (H&S 11161)

3. Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the board; the board may approve security printer applications after the board has completed a state and federal criminal background check. (H&S 11161.5)

4. Provides that the board or the Department of Justice (DOJ) may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime. (H&S 11161.5)

5. Provides that prescription forms shall be printed with specified features. (H&S 11162.1)

6. Provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified. (H&S 11190)

This Bill:

This bill would make several changes to facilitate the operation of Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) and to allow for consistency with existing DOJ policy and practice and conformity with "best practices" model to prevent diversion of controlled substances. The bill would make the following changes:

1. Transfers responsibility from the board to DOJ to control the manner in which fingerprints are provided when conducting criminal background investigations of vendors applying to print security prescription forms.

   a. Allows DOJ to collect fees.

   b. Extends from 30 days to 60 days the period with which DOJ may deny an application.

c. Allows DOJ to retain fingerprint impressions for subsequent enforcement and arrest.

d. Allows DOJ and the board to examine the books of security printers.

(H&S 11161.5 Amended)

2 Allows the terminally ill exemption (allowing a prescriber to use nonsecurity forms) for any controlled substance prescription. (Current law designates only C II drugs can be prescribed in this manner.) (H&S 11159.2 Amended)

3. Authorizes the Superior Court to order a prescriber not to order, obtain, or use any prescription forms during a pending criminal action. (H&S 11161 Amended)

4. Clarifies that DOJ is solely responsible for determining whether security printer applications are complete, for maintaining a list of approved security printers, and for revoking approval of security printers. (H&S 11161.5 Amended)

5. Clarifies how prescribers and physician assistants can state number of prescriptions included on form and otherwise comply with CURES program. (H&S 11162.1 Amended)

6. Requires prescribers to pre-print their specific schedule II prescribing privileges and to a check a box by the name of the prescriber writing the prescription. (H&S 11161 Amended)

7. Requires approved security printers to print forms with a vendor identification code issued by the DOJ. (H&S 11162.1 Amended)

8 Requires pharmacists to indicate method of payment from patients for each schedule II or III controlled substance purchased into CURES. Also prescribers who dispense C II and CIII must report this as well too. (H&S 11165 Amended)

9 Requires direct dispensers of controlled substances to submit information to the DOJ in a format specified by the DOJ. (H&S 11190 Amended)

10. Makes other technical changes to allow for consistency with existing DOJ policy and practice.

Comment:

1) Author's Intent. The bill is sponsored the DOJ. The author's intent is to make technical and clean-up changes to facilitate the effective operation of the CURES and the program duties of the Bureau of Narcotics Enforcement. Additionally, this bill would make technical changes to be consistent with existing DOJ policy and practice and conform to their "best practices" model to prevent diversion of controlled substances.

2) Above and Beyond Current Requirements: Provisions in AB 734 go beyond transferring oversight of the security printer program from the board to DOJ. New provisions would:

a. Expand DOJ authority to:

   i. Retain the figure prints of applicants.

   ii. Extend the time to review security printer applications from 30 to 60 days.

   iii. Deny an application for a security printer if an applicant is found to have been convicted of a crime or if the applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime.

iv. Inspect a security printer's business, or examine books and records anytime during regular business hours.

b. Expand information required on prescription forms to include:
   i. Checkboxes for schedule II-V for prescriber's authority.
   ii. Identification number of security printer.

c. Require pharmacies to inform DOJ by inputting into CURES of the method of payment used by patients to purchase schedule II and III drugs.

This bill expands and alters the components required on a security form. It expands the information pharmacies must submit to CURES.

The board submitted a modification to section 11165 to cap the board's funding to CURES at the amount approved by the Governor and the Legislature. This amendment needs to be included in the bill. (See attached.)

Many of these requirements seem excessive. Specifically, the requirement that prescription forms list the schedule of drugs a prescriber can prescribe. There is no means for a pharmacist to check if a prescriber is prescribing out of class. Additionally, what happens if a prescriber's authority changes? Would the prescriber be obligated to use new forms with updated prescribing authority? There does not appear to be a benefit from having this information on prescription forms.

3) Proposed Amendments.

a. Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ.

b. Delete the requirement that the privileges of a practitioner to prescribe controlled substances be printed on the prescription form. (Page 10, lines 10-19).

c. Delete the requirement that a pharmacist must report to the DOJ the method of payment used by a customer when purchasing Schedule II and III drugs. (Page 13, line 5).

4) Previous Legislation. SB 151 (Burton, 2003, Chapter 406) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

5) History.

2005

Apr. 14	From committee: Do pass as amended, but first amend, and re-refer to Com. on PUB. S. (Ayes 6. Noes 0.)
Apr. 6	Set for hearing April 13.
Apr. 4	Set, first hearing. Hearing canceled at the request of author.
Mar. 16	Set for hearing April 6.
Mar. 10	To Coms. on HEALTH and PUB. S.
Feb. 23	From print. May be acted upon on or after March 25.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Proposed Amendments to CURES Statutory Provisions for Budgetary Issues

SECTION 1. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate ~~funds~~ appropriations from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. Payment from any of the above special funds for costs that exceed budgeted amounts is contingent upon receiving appropriation augmentations sufficient to cover the full costs billed by the Department of Justice.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number;
federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

BILL ANALYSIS
SB 734

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

AUTHOR: Torlakson
AMENDED: As introduced and as proposed to be amended
HEARING DATE: April 13, 2005
FISCAL: Public Safety / Appropriations
CONSULTANT:
Machi / ak

SUBJECT

Controlled substances

SUMMARY

This bill makes various technical and clarifying changes to the Health and Safety Code pertaining to the Controlled Substance Utilization Review and Evaluation System.

ABSTRACT

Existing law:
1.Establishes until July 1, 2008 the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring by the Department of Justice (DOJ) of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these substances.

2.Requires that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

3.Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy. The Board of Pharmacy may approve security printer applications after the applicant has provided specific information and fingerprints, in a manner specified by the Board. The required information is used for the purpose of completing state and federal criminal background checks.

4.Provides that the Board of Pharmacy or DOJ may deny a

security printer application for specific reasons, including where the applicant has been convicted of a crime.

5.Provides that prescription forms shall be printed with specific features.

6.Provides that with respect to specific controlled substances, each dispensing pharmacy or prescriber shall provide specific information to DOJ.

7.Provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor.

8.States a prescription for a schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill:

1.Removes the reference to schedule II controlled substances in Health and Safety Code Section 11159.2 to ensure that terminally ill patients can receive a prescription for illnesses, such as cancer or HIV, that contain not only Schedule II drugs but also compounds or combinations from all Schedules, which can be written on the same prescription. This will ensure pharmacists will fill such prescriptions without disruption.

2.Authorizes the superior court to order a prescriber not to order or obtain or use any additional prescription forms during a pending criminal action and requires the law enforcement agency obtaining such an order to notify DOJ.

3.Specifies that DOJ, and not the Board of Pharmacy, will control the manner in which fingerprints are provided.

4.Allows DOJ to collect a fee for processing criminal background checks when a vendor applies to become an approved security printer of prescription forms. Each applicant shall pay, at the time of filing an application for a permit, a fee determined by DOJ that will not exceed the application processing costs of DOJ.

5.Specifies and defines the security printer applicant class that must submit criminal background checks as any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms.

6.Authorizes DOJ to examine the books and records of any applicant or visit and inspect a certified security printer.

7.Directs security prescription form printers to submit a sample of their secure prescription forms to DOJ.

8.Requires an approved security printer to print their security prescription forms with a vendor identification code issued by DOJ.

9.Requires a check box by the name of each prescriber on a security prescription form to be checked to identify the prescriber issuing the prescription when there are multiple prescribers on one security prescription form.

10. Allows a prescriber designated by a license health care facility, licensed clinic or other clinic exempt from licensure to order controlled substance prescription forms for use by prescribers when treating patients in that facility. This would also allow the licensed clinic or clinic exempt from licensure to avoid specified printing requirements that appear on the security prescription form.

11. Requires a designated prescriber to meet the requirements adding licensed clinic or clinic exempt from licensure pursuant to Health and Safety Code 1206 preprinted on the form.

12. Clarifies, by striking out text and allowing for a simple pre-printed statement on the bottom of prescription blanks that "Prescription is void if the number of drugs is not noted."

13. Requires a prescriber who directly dispenses controlled substances to submit the information to DOJ in a format set by DOJ pursuant to regulation.

FISCAL IMPACT

Unknown.

BACKGROUND

According to the author, the purpose of the bill is to strengthen the CURES program and clarify the roles of the Board of Pharmacy and Bureau of Narcotics Enforcement with the ultimate goal of preventing the diversion of controlled substances.

Under existing federal and state laws, controlled

substances are ranked according to their potential for abuse, accepted medical use, and safety under medical supervision. Schedule I substances (e.g. heroin and LSD) have high potential for abuse, no currently accepted medical use, and lack accepted safety for use. Schedule II drugs (e.g. morphine, codeine, Demerol, and Percodan) have a high potential for abuse and high potential for physical or psychological dependence if used improperly, but have accepted medical value in treating pain.

Schedule III drugs (e.g. Vicodin, anabolic steroids, codeine with aspirin or Tylenol), schedule IV drugs (e.g. Darvon, Valium, Halcyon, and Xanax), and schedule V drugs (over the counter cough medicines with codeine) generally have less potential for abuse than schedule I or II drugs, have accepted medical use in treatment, and lower potential for physical or psychological dependence.

The Bureau of Narcotic Enforcement within DOJ currently administers and enforces the multiple copy prescription surveillance program and is responsible for all state controlled substance enforcement activities.

The CURES program was established in 1997 by AB 3042 (Takasugi) in response to recommendations of the Controlled Substance Prescription Advisory Council established by SCR 74 in 1992. The purpose of CURES was to provide for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances. CURES provides for the electronic transmission of Schedule II prescription data to DOJ at the time prescriptions are dispensed.

CURES was established as a three-year pilot project, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies of the two systems. Subsequent legislation extended the sunset on the program to July 1, 2008. A report to the Legislature by DOJ and the Board of Pharmacy in 1999 recommended that CURES be made a permanent program.

Arguments in support
According to the sponsor, the Attorney General, this bill addresses needed technical and administrative changes to existing state law. DOJ sponsors these changes to assist in the permanent operation of CURES within the CURES program. The changes remove inconsistencies within SB 151 and provide that DOJ policy and practice will conform with the "best practices" model to prevent diversion of controlled substances.

SB151 brought forth significant changes to the CURES

program. One of the major changes was the elimination of the 65-year-old triplicate prescription form. The form was replaced with a new secure, tamper-resistant prescription form for Schedules II through IV controlled substances. In addition, CURES was also authorized to collect Schedule III prescription information.

This bill attempts to amend several sections of the Health and Safety Code as it relates to controlled substances, the facilitation of the ongoing operation of CURES, and continued efforts by law enforcement in preventing the diversion and abuse of prescription drugs.

Arguments in opposition
The California Medical Association (CMA) has taken an oppose unless amended position on this measure and is asking for amendments to address the following:

Provisions to address current training methodologies for residents, fellows and interns who do not have all of the required information that must be included on the security prescription pads but are legally prescribing controlled substances. There is some agreement in principle to work with the training facilities to develop new procedures.

Clarify that a prescription for a terminally ill patient shall be filled with any controlled substance even if there is a technical error on the prescription. Current law only allows for this provision for a schedule II controlled substance. (This provision has been addressed in amendments to SB 734).

Remove the expansion to schedule III through V drugs. The impetus for SB 151 was to remove the barriers physicians encountered when prescribing schedule II substances, generally for pain management, while being conscientious of law enforcement beliefs regarding potential drub diversion. However, under the secure prescription pad system new barriers have risen. As the new pads must be used for all controlled substances, there has been a noticeable dip in the number or prescriptions written for schedule III-V controlled substances. As there is little evidence that these drugs are often diverted, the need to be on a secure pad is negligible. CMA believes that the interests of quality health care outweigh the need for secure pads, especially for Schedule III-V substances.

Current law allows a physician or surgeon to submit prescriptions electronically however; the security pads require latent " void" pattern to appear when

prescriptions are faxed. They believe that this is nonsensical. CMA would prefer for the latent void requirement to be eliminated, but for the short term it must be made clear that prescriptions shall be filled even if the latent void pattern has been activated. There is some agreement that they would only be filled if there are some efforts on the part of the pharmacist to ensure the validity of the prescription.

Prior legislation

AB 3042 (Takasugi, Chapter 738, Statutes of 1996. Created the CURES program on a pilot basis.

AB 2693 (Migden, Chapter 789, Statutes of 1998 . Exempts Schedule II controlled substances for patients with terminal illnesses from triplicate prescription form requirements.

SB 1308 (Senate Business and Professions Committee, Chapter 655, Statutes of 1999. Extends the sunset date on the CURES program to July 1, 2003 and requires DOJ to submit annual status reports on the program to the Legislature.

SB 1000 (Johannessen, 2001) . Would have provided a study of the CURES system and allowed licensed health care providers to access CURES information. This measure was vetoed by the Governor.)

AB 2018 (Thomson, Chapter 1092, Statutes of 2002. Provides changes to the triplicate pad and establishes a process for correction of prescription errors.

AB 2655 (Matthews, Chapter 343, Statutes of 2002 . Extends the CURES program to 2008 and provides access to CURES data by licensed health care providers.

SB 151 (Burton, Chapter 406, Statutes of 2004 . Eliminates the July 1, 2008 sunset date on CURES administered by DOJ, eliminates, effective July 1, 2004, the requirement that Schedule II controlled substances (morphine, Percodan, etc.) prescriptions be written on triplicate forms, and adds a requirement that Schedule III controlled substances (codeine with aspirin, steroids, etc.) be included in the CURES system.

POSITIONS

Support: Attorney General Bill Lockyer (sponsor)

Oppose:California Medical Association

Attachment 5

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AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 21

Introduced by Assembly Member Levine
(Coauthors: Assembly Members *Berg,* Chavez, Cohn, *De La Torre,* Evans, Goldberg, Jones, Koretz, Laird, Lieber, Montanez, Nava, and Ruskin)

December 6, 2004

An act to add Section 4069 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 21, as amended, Levine. Pharmacists: ~~prescriptions~~ *dispensing requirements.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of that law a crime. Under existing law, a prescription may be lawfully dispensed only by a pharmacist, unless otherwise specified by the Pharmacy Law.

This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline ~~to dispense a prescription~~ on ethical, moral, or religious grounds *to dispense a drug pursuant to a lawful request* only if he or she satisfies certain conditions. The bill would ~~require revocation of the pharmacist's license for~~ *make* a violation of its provisions *unprofessional conduct, subject to disciplinary action by the board.*

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4069 is added to the Business and Professions Code, to read:

4069. (a) Notwithstanding any other provision of law, a pharmacist shall dispense a lawful prescription unless one of the following circumstances exists:

(1) The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

(2) The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

(3) (A) The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to ~~an order or prescription~~ *a lawful request.* A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing ~~of the drug or class of drugs to which he or she objects. The~~ *of his or her objections. The* pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

~~(B) A pharmacist electing not to dispense a drug as described in subparagraph (A) shall take either of the following actions:~~

~~(i) Upon the patient's request, return the prescription to the patient and refer him or her to a pharmacy that has the drug in stock.~~

~~(ii) Verbally verify, while the patient is waiting for the prescription to be dispensed, that another pharmacy has the drug in stock and will dispense it to the patient, promptly transfer the prescription to that pharmacy, and immediately provide this information to the patient.~~

~~(b) The board shall revoke the license of a pharmacist who violates this section.~~

(B) An employer shall, upon receipt of the notification described in subparagraph (A), establish a policy and protocol to accommodate the patient's needs for the drug.

(b) An employer shall not withdraw an offer of employment or terminate employment based on the notification or change in the notification, as described in subparagraph (A) of paragraph (3) of subdivision (a).

(c) A violation of this section by a pharmacist constitutes unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 21 **VERSION: AMENDED APRIL 13, 2005**

AUTHOR: LEVINE **SPONSOR: LEVINE**

RECOMMENDED POSITION:

SUBJECT: PHARMACISTS: DISPENSING REQUIREMENTS

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052(8))

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

4) Requires the board to take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. (B&P 4301)

This Bill:

1) Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:

a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

b. The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request.

   i. A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing of his or her objections.

   ii. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

2) Requires an employer, upon receipt of a pharmacist objections, to establish a policy and protocol to accommodate the patient's needs for the drug.

3) Does not permit an employer to withdraw an offer of employment or terminate employment based on the notification or change in the notification.

4) Requires a violation of this section by a pharmacist to constitute unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board.

(B&P 4069 Added)

Comment:

1) Author's Intent. The author's intent is to insure that pharmacists do not refuse to dispense EC to patients.

2) In the News. The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. (see attached article) While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

3) Enforcement. Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. Consequently, if AB 21 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

4) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

5) Related Legislation. AB 644 (Ortiz 2005) Dispensing Prescription Drugs And Devices, would require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate.

6) Support & Opposition.

Support: California Alliance for Consumer Protection
California Medical Association

Opposition: California Family Alliance
California Right to Life Committee, Inc.
Capitol Resource Institute

7) History.

2005
Apr. 13 Read second time and amended.
Apr. 12 From committee: Amend, do pass as amended, and re-refer to Com. onB. & P. (Ayes 10. Noes 3.) (April 5).
Mar. 30 Re-referred to Com. on HEALTH.
Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004
Dec. 7 From printer. May be heard in committee January 6.
Dec. 6 Read first time. To print.

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washingtonpost.com

Pharmacists' Rights at Front Of New Debate

Because of Beliefs, Some Refuse To Fill Birth Control Prescriptions

By Rob Stein
Washington Post Staff Writer
Monday, March 28, 2005; Page A01

Some pharmacists across the country are refusing to fill prescriptions for birth control and morning-after pills, saying that dispensing the medications violates their personal moral or religious beliefs.

The trend has opened a new front in the nation's battle over reproductive rights, sparking an intense debate over the competing rights of pharmacists to refuse to participate in something they consider repugnant and a woman's right to get medications her doctor has prescribed. It has also triggered pitched political battles in statehouses across the nation as politicians seek to pass laws either to protect pharmacists from being penalized -- or force them to carry out their duties.

"This is a very big issue that's just beginning to surface," said Steven H. Aden of the Christian Legal Society's Center for Law and Religious Freedom in Annandale, which defends pharmacists. "More and more pharmacists are becoming aware of their right to conscientiously refuse to pass objectionable medications across the counter. We are on the very front edge of a wave that's going to break not too far down the line."

An increasing number of clashes are occurring in drugstores across the country. Pharmacists often risk dismissal or other disciplinary action to stand up for their beliefs, while shaken teenage girls and women desperately call their doctors, frequently late at night, after being turned away by sometimes-lecturing men and women in white coats.

"There are pharmacists who will only give birth control pills to a woman if she's married. There are pharmacists who mistakenly believe contraception is a form of abortion and refuse to prescribe it to anyone," said Adam Sonfield of the Alan Guttmacher Institute in New York, which tracks reproductive issues. "There are even cases of pharmacists holding prescriptions hostage, where they won't even transfer it to another pharmacy when time is of the essence."

That is what happened to Kathleen Pulz and her husband, who panicked when the condom they were using broke. Their fear really spiked when the Walgreens pharmacy down the street from their home in Milwaukee refused to fill an emergency prescription for the morning-after pill.

"I couldn't believe it," said Pulz, 44, who with her husband had long ago decided they could not afford a fifth child. "How can they make that decision for us? I was outraged. At the same time, I was sad that we had to do this. But I was scared. I didn't know what we were going to do."

Supporters of pharmacists' rights see the trend as a welcome expression of personal belief. Women's groups see it as a major threat to reproductive rights and one of the latest manifestations of the religious right's growing political reach -- this time into the neighborhood pharmacy.

"This is another indication of the current political atmosphere and climate," said Rachel Laser of the National Women's Law Center in Washington. "It's outrageous. It's sex discrimination. It prevents access to a basic form of health care for women. We're going back in time."

The issue could intensify further if the Food and Drug Administration approves the sale of the Plan B morning-after pill without a prescription -- a controversial step that would likely make pharmacists the primary gatekeeper.

The question of health care workers refusing to provide certain services first emerged among doctors, nurses and other health care workers over abortions. The trend began to spread to pharmacists with the approval of the morning-after pill and physician-assisted suicide in Oregon, with support from such organizations as the U.S. Conference of Catholic Bishops and Pharmacists for Life International, which claims 1,600 members on six continents. Its members are primarily in the United States, Canada and Britain.

"Our group was founded with the idea of returning pharmacy to a healing-only profession. What's been going on is the use of medication to stop human life. That violates the ideal of the Hippocratic oath that medical practitioners should do no harm," said Karen L. Brauer, president of Pharmacists for Life, who was fired from a Kmart pharmacy in Delhi, Ohio, for refusing to fill birth control prescriptions.

No one knows exactly how often that is happening, but cases have been reported across the country, including in California, Washington, Georgia, Illinois, Louisiana, Massachusetts, Texas, New Hampshire, Ohio and North Carolina. Advocates on both sides say the refusals appear to be spreading, often surfacing only in the rare instances when women file complaints.

Pharmacists are regulated by state laws and can face disciplinary action from licensing boards. But the only case that has gotten that far involves Neil T. Noesen, who in 2002 refused to fill a University of Wisconsin student's birth control pill prescription at a Kmart in Menomonie, Wis., or transfer the prescription elsewhere. An administrative judge last month recommended Noesen be required to take ethics classes, alert future employers to his beliefs and pay what could be as much as $20,000 to cover the costs of the legal proceedings. The state pharmacy board will decide whether to impose that penalty next month.

"He's a devout Roman Catholic and believes participating in any action that inhibits or prohibits human life is a sin," said Aden of the Christian Legal Society. "The rights of pharmacists like him should be respected."

Wisconsin is one of at least 11 states considering "conscience clause" laws that would protect pharmacists such as Noesen. Four states already have laws that specifically allow pharmacists to refuse to fill prescriptions that violate their beliefs. At the same time, at least four states are considering laws that would explicitly require pharmacists to fill all prescriptions.

The American Pharmacists Association recently reaffirmed its policy that pharmacists can refuse to fill prescriptions as long as they make sure customers can get their medications some other way.

"We don't have a profession of robots. We have a profession of humans. We have to acknowledge that individual pharmacists have individual beliefs," said Susan C. Winckler, the association's vice president for policy and communications. "What we suggest is that they identify those situations ahead of time and have an alternative system set up so the patient has access to their therapy."

The alternative system can include making sure another pharmacist is on duty who can take over or making sure there is another pharmacy nearby willing to fill the prescription, Winckler said. "The key is that it should be seamless and avoids a conflict between the pharmacist's right to step away and the patient's right to obtain their medication," she said.

Brauer, of Pharmacists for Life, defends the right of pharmacists not only to decline to fill prescriptions themselves but also to refuse to refer customers elsewhere or transfer prescriptions.

"That's like saying, 'I don't kill people myself but let me tell you about the guy down the street who does.' What's that saying? 'I will not off your husband, but I know a buddy who will?' It's the same thing," said Brauer, who now works at a hospital pharmacy.

Large pharmacy chains, including Walgreens, Wal-Mart and CVS, have instituted similar policies that try to balance pharmacists' and customers' rights.

"We obviously do have pharmacists with individual moral and ethical beliefs. When it does happen, the pharmacist is asked to notify the manager that they have decided not to fill the prescription, and the manager has the obligation to make sure the customer has access to the prescription by another means," said Tiffany Bruce, a spokeswoman for Walgreens. "We have to respect the pharmacist, but we have to also respect the right of the person to receive the prescription."

Women's advocates say such policies are impractical, especially late at night in emergency situations involving the morning-after pill, which must be taken within 72 hours. Even in non-urgent cases, poor women have a hard time getting enough time off work or money to go from one pharmacy to another. Young women, who are often frightened and unsure of themselves, may simply give up when confronted by a judgmental pharmacist.

"What is a woman supposed to do in rural America, in places where there may only be one pharmacy?" asked Nancy Keenan, president of NARAL Pro-Choice America, which is launching a campaign today to counter the trend. "It's a slap in the face to women."

By the time Suzanne Richards, 21, finally got another pharmacy to fill her morning-after pill prescription -- after being rejected by a drive-through Brooks Pharmacy in Laconia, N.H., one late Saturday night in September -- the 72 hours had long passed.

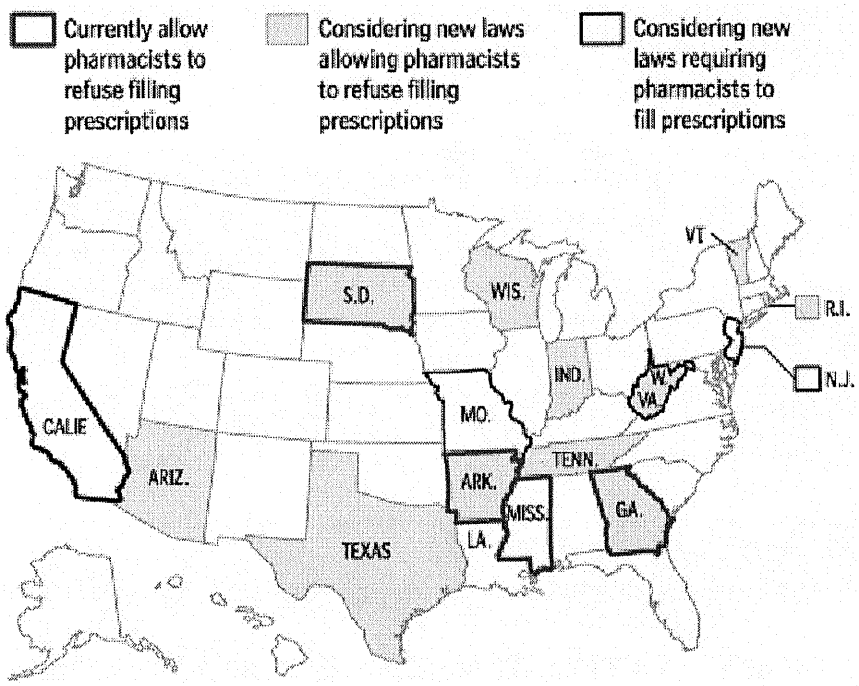
"When he told me he wouldn't fill it, I just pulled over in the parking lot and started crying," said Richards, a single mother of a 3-year-old who runs her own cleaning service. "I just couldn't believe it. I was just trying to be responsible."

In the end, Richards turned out not to be pregnant, and Pulz was able to obtain her prescription last June directly from her doctor, though she does not think she was pregnant, either.

"I was lucky," Pulz said. "I can sympathize with someone who feels strongly and doesn't want to be involved. But they should just step out of the way and not interfere with someone else's decision. It's just not right."

No Refills

A number of states have either passed laws or are considering laws that allow pharmacists to refuse to fill prescriptions, such as birth control and morning-after pills, that they feel violate their personal, moral or religious beliefs.



JavaScript is required to display this interactive graphic. If it is turned off, please enable JavaScript in your browser preferences.
SOURCE: National Women's Law Center | The Washington Post

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AMENDED IN SENATE APRIL 7, 2005

SENATE BILL No. 644

Introduced by Senator Ortiz

February 22, 2005

An act to add Section ~~4050.1~~ *733* to the Business and Professions Code, relating to ~~pharmacists~~ *healing arts*.

LEGISLATIVE COUNSEL'S DIGEST

SB 644, as amended, Ortiz. Dispensing ~~of prescriptions~~ *prescription drugs and devices*.

Existing law~~, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of those provisions a crime. Existing law prohibits, except as specified, a person other than a pharmacist from dispensing a dangerous drug, as defined, pursuant to a prescription~~ *makes certain actions by a health care professional unprofessional conduct subject to disciplinary action by the licensing board regulating the health care professional*.

This bill would ~~require a pharmacist to dispense a lawful prescription~~ *include within those provisions, a requirement that a health care licentiate dispense drugs and devices pursuant to a lawful prescription or order* except in specified circumstances, including on ethical, moral, or religious grounds asserted by the ~~pharmacist~~ *licentiate*. The bill would authorize the ~~pharmacist~~ *licentiate* to decline to dispense the prescription *or order* on that basis only if *the licentiate notified* his or her employer ~~is able to reasonably accommodate that objection~~ *of the objection and it can be reasonably accommodated*.

~~Because violation of the bill would be a crime, it would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.~~

~~Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

~~SECTION 1. The Legislature finds and declares the following:~~

~~(a) Patients should have timely access to medications that are lawfully prescribed for them.~~

~~(b) When engaging in the practice of pharmacy, a pharmacist must exercise professional judgment in the best interest of a patient's health and respect a patient's dignity and autonomy and maintain the confidentiality of a patient's medical information.~~

SECTION 1. It is the intent of the Legislature that health care professionals dispense prescription drugs and devices in a timely way or provide appropriate referrals for patients to obtain the necessary prescription drugs and devices, despite the health care professional's objection to dispensing the drugs or devices on ethical, moral, or religious grounds.

~~SEC. 2. Section 4050.1 is added to the Business and Professions Code, to read:~~

~~4050.1.~~

SEC. 2 Section 733 is added to the Business and Professions Code, to read:

733. Notwithstanding any other provision of law, a ~~pharmacist shall dispense a lawful prescription unless one of the~~ *licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the* following circumstances exists:

(a) Based on the ~~pharmacist's~~ *licentiate's* professional training and judgment, dispensing *pursuant to the order or* the prescription is contrary to law or is contraindicated for the patient.

(b) The pharmacy does not have the ~~dangerous drug that was prescribed~~ *prescription drug or device* in its stock. ~~The pharmacist shall immediately~~ *If an order or prescription can not*

be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(1) Immediately notify the patient and ~~promptly~~ *arrange for the drug or device to be delivered to the pharmacy or directly to the patient in a timely way.*

(2) Promptly transfer the prescription to another pharmacy known to stock the ~~dangerous drug or, upon the patient's request, return~~ *prescription drug or device and that is within a reasonable distance from the pharmacy that is transferring the prescription or order to ensure the patient has timely access to the drug or device.*

(3) Return the prescription to the patient and refer the patient to a pharmacy known to stock the ~~dangerous drug~~ *prescription drug or device and that is within a reasonable distance from the referring pharmacy to ensure that the patient has timely access to the drug or device.*

(c) The ~~pharmacist~~ *licentiate* refuses on ethical, moral, or religious grounds to dispense a ~~dangerous drug~~ *drug or device* pursuant to an order or prescription. A ~~pharmacist~~ *licentiate* may decline to dispense a ~~dangerous drug~~ *prescription drug or device* on this basis only ~~after notifying~~ *if the licentiate has previously notified* his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the ~~pharmacist's~~ *licentiate's* employer can, without creating undue hardship, ~~including undue hardship to the patient,~~ provide a reasonable accommodation of the ~~pharmacist's~~ *licentiate's* objection by establishing protocols that ensure that the patient has timely access to the prescribed ~~dangerous drug~~ *drug or device* despite the ~~pharmacist's~~ *licentiate's* refusal to dispense the prescription *or order*. For purposes of this subdivision, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision ~~(j)~~*(1)* of Section 12940 of the Government Code~~, and "dangerous drug"~~.

(d) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022 and includes the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because~~

~~the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 644 **VERSION: AMENDED APRIL 7, 2005**

AUTHOR: ORTIZ **SPONSOR: PLANNED PARENTHOOD**

RECOMMENDED POSITION:

SUBJECT: DISPENSING PRESCRIPTION DRUG AND DEVICES

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052 (8))

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

This Bill:

1) Requires a licentiate to dispense drugs and devices pursuant to a lawful order or prescription unless one of the following circumstances exists:

a. Based on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law or is contraindicated for the patient.

b. The pharmacy does not have the prescription drug or device in its stock. If an order or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

i. Immediately notify the patient and arrange for the drug or device to be delivered to the pharmacy or directly to the patient in a timely way.

ii. Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device and that is within a reasonable distance from the pharmacy that is transferring the prescription or order to ensure the patient has timely access to the drug or device.

iii. Return the prescription to the patient and refer the patient to a pharmacy known to stock the prescription drug or device and that is within a reasonable distance from the referring pharmacy to ensure that the patient has timely access to the drug or device.

c. The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, if:

i. The licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects; and

ii. The licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection by establishing protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order.

2) Defines "reasonable accommodation" and "undue hardship" in accordance with the Government Code.

(B&P 733 Added)

Comment:

1) Author's Intent. The sponsor intent is to establish in law a duty to fill lawful prescriptions while balancing a licensees right to ethical, moral or religious objections with a patient's right to basic health care.

2) In the News. The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

3) Enforcement. Enforcement of SB 644 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacists' refusal to dispense EC. Consequently, if SB 644 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

4) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

5) Related Legislation. AB 21 (Levine 2005) Pharmacists: Dispensing Requirements, would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she has notified his or her employer in writing. The bill would make *a* violation of its provisions unprofessional conduct, subject to disciplinary action by the board.

6) History.

2005

Apr. 12	Reset for hearing April 27 in HEALTH pending receipt.
Apr. 11	Set for hearing April 20 in HEALTH pending receipt.
Apr. 7	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 17	Set for hearing April 11.
Mar. 3	To Coms. on B., P. & E.D. and HEALTH
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Attachment 6

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AMENDED IN ASSEMBLY APRIL 13, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 283

Introduced by Assembly Member Koretz
(Coauthor: Assembly Member Maze)
(~~Coauthor: Senator Margett~~ *Coauthors: Senators Alquist and Margett*)

February 9, 2005

An act to add Section 11100.01 to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 283, as amended, Koretz. ~~Pseudoephedrine~~ *Ephedrine and pseudoephedrine*: retail sale.

(1) Under existing law, a retailer who makes an over-the-counter retail sale of *ephedrine or* pseudoephedrine is generally subject to a 3 package per transaction limitation or 9 gram per transaction limitation. Any violation of this requirement is a crime, punishable as specified.

This bill would provide that the dispensing, sale, or distribution at retail of any compound, mixture, or preparation containing any detectable quantity of *ephedrine,* pseudoephedrine*, or any derivative of ephedrine or pseudoephedrine* shall be subject to specified additional requirements. The *retailer would be required to store and display the product in a locked cabinet or area, as specified, and the* transaction would be required to be made ~~in a pharmacy located and currently licensed in this state and~~ by a ~~pharmacist or pharmacy technician who is currently licensed in this state~~ *retailer or employee of a retailer who meets specified requirements*. Before distributing or selling any product to a purchaser, ~~the pharmacist, pharmacy technician, or pharmacy clerk~~ *a retailer or the employee of a retailer* would be required to request government issued photo identification

from the purchaser and to obtain specified information to be ~~recorded in a written transaction log or receipt. The pharmacy would be required to maintain the information for at least 3 years from the date of purchase such that the information would be readily retrievable and available to law enforcement upon request during the pharmacy's normal operating hours~~ *reported to the Department of Justice, as specified; the bill would prohibit the information obtained from being provided to any person or entity, except as specified.* A violation of any of these provisions would be a misdemeanor, punishable as specified, *except that a retail clerk who fails to request photo identification or obtain the required information would not be subject to any civil, criminal, or other penalty, unless the clerk is a willful participant in an ongoing criminal conspiracy to violate these provisions*. By creating new crimes, this bill would impose a state-mandated local program upon local governments.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11100.01 is added to the Health and Safety Code, to read:

11100.01. (a) In addition to any requirement specified in Section 11100, the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of ~~pseudoephedrine~~ *ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine*, or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of ~~pseudoephedrine~~ *ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine*, shall be subject to the following requirements:

~~(1) The dispensing, sale, or distribution at retail of any product specified in subdivision (a) shall be made in a pharmacy located and currently licensed in this state.~~

(1) Any product specified in subdivision (a) shall be stored or displayed by a retailer in a locked cabinet or locked area in such a manner that the product is accessible to the public only with the assistance of the retailer or employee of the retailer. The retailer or employee of the retailer shall at all times act to prevent the theft or diversion of the product.

(2) The dispensing, sale, or distribution at retail of any product specified in subdivision (a) shall be made only by a ~~pharmacist or pharmacy technician who is currently licensed in this state or by a pharmacy clerk under the supervision of a currently licensed pharmacist or pharmacy technician.~~ *retailer or employee of a retailer who is trained in the legal requirements set forth in this section and who shall at all times act to prevent the theft or diversion of the product and the unlawful sharing of information obtained pursuant to subdivision (b).*

(b) Before distributing or selling any product specified in subdivision (a) to a purchaser, a ~~pharmacist, pharmacy technician, or a pharmacy clerk~~ *retailer or employee of a retailer* shall request government issued photo identification from the purchaser and shall obtain the following information to be ~~recorded in a written transaction log or receipt~~ *reported to the Department of Justice in a frequency and format specified by the Department of Justice*:

(1) Date of purchase.

(2) Name and amount of product purchased.

(3) Government issuer of the photo identification.

(4) Identification number.

(5) Purchaser's full name ~~printed in legible form~~ *as it appears on the photo identification.*

(6) Purchaser's signature.

~~(c) The pharmacy shall maintain the written transaction log or receipt for at least three years from the date of purchase either in an automated data-processing or manual record mode such that the information is readily retrievable and available to law enforcement upon request during the pharmacy's normal operating hours.~~

(c) Information obtained pursuant to subdivision (b) shall only be provided to appropriate state, local, or federal person or public agency with respect to a disciplinary, civil, or criminal action related to a violation of this section or to the unlawful

manufacture of methamphetamine or any other controlled substance.

(d) This section shall not apply to any ~~compound, mixture, or preparation~~ *product specified in subdivision (a)* in liquid, liquid capsule, or ~~gel capsule~~ *dissolvable strip* form in which ~~pseudoephedrine is not the only active ingredient.~~ *ephedrine, pseudoephedrine, or any derivative of ephedrine or pseudoephedrine is the active ingredient.*

(e) (1) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that exempt a substance from the application of subdivision (a) if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

(2) The Department of Justice shall, upon satisfactory application by the manufacturer of a drug product to the department, exempt any product the department determines to have been formulated in such a way as to effectively prevent the conversion of any active ingredient in the product into methamphetamine or any other controlled substance.

~~(f) (1) A first violation of this section is a misdemeanor.~~

(f) Except as provided in subdivision (g), any person who violates this section shall be punished as follows:

(1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section or Section 11100 shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(g) *(1) Notwithstanding subdivision (f) and except as provided in paragraph (2), a retail clerk who fails to request photo identification or obtain the information specified in subdivision (b) shall not be guilty of a crime pursuant to subdivision (f), shall not be subject to any civil penalty, and shall not be subject to any disciplinary action or discharge by his or her employer.*

(2) This subdivision shall not apply to a retail clerk who is a willful participant in an ongoing criminal conspiracy to violate this section.

(h) It is the intent of the Legislature that this section and Section 11100 shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing pseudoephedrine.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 283 **VERSION: APRIL 13, 2005**

AUTHOR: KORETZ **SPONSOR: KORETZ**

RECOMMENDED POSITION:

SUBJECT: EPHEDRINE AND PSEUDOEPHEDRINE: RETAIL SALE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Requires that the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, of or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine, shall be subject to the following requirements:

a. The products be stored or displayed by a retailer in a locked cabinet or locked area in such a manner that the product is accessible to the public only with the assistance of the retailer or employee of the retailer. The retailer or the employee of a retailer shall act to prevent the theft or diversion of the products.

b. The sale of products shall be made only by a retailer or employee of a retailer who is trained in the legal requirements set forth in this section and who shall at all times act to prevent the theft or diversion of the products.

c. Before distributing or selling any product to a purchaser, retailer or employee of the retailer shall request a government issued photo identification from the purchaser and shall obtain the following information to be reported to the Department of Justice (DOJ) in a frequency and format specified by DOJ:

   i. Date of purchase.
   ii. Name and amount of product purchased.
   iii. Government issuer of the photo identification.
   iv. Identification number.

v. Purchaser's full name as it appears on the photo identification.
vi. Purchaser's signature.

2) Sets the following penalties for any person who violate the measure:
   a. A first violation of the measure would be a misdemeanor.
   b. Subsequent violations and convictions would be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

3) Specifies that a retail clerk who fails to request photo identification or obtain other specified information for the sale, will not be guilty of a crime, or subject to civil penalties, or disciplinary action or discharge by his or her employer.

4) Allows the DOJ to adopt rules and regulations that exempt a drug product if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

5) This measure would not apply to any product in liquid, liquid capsule, or dissolvable strip form in which ephedrine, pseudoephedrine, or any derivative ephedrine or pseudoephedrine is not the only active ingredient.

(H&S 11100.01 Added)

Comment:

1) Author's Intent. The author's intent is to reduce the proliferation of methamphetamine (meth) user labs by limiting the availability of ephedrine and pseudoephedrine; an ingredient used in making meth. (A user lab is a small-scale meth production lab that supplies one to a few meth users.)

The author's district includes the City of West Hollywood, where meth has become the party drug of choice the in the gay male community. Author's staff states that a person taking meth is three times as more likely then someone not taking the drug to test positive for HIV.

2) Amended on April 13, 2005. The introduced version of AB 283 would have required sales of pseudoephedrine to be made by a licensed pharmacist, pharmacy technician, or clerk. The April 13th version of the bill deletes this requirement.

3) DOJ Tracks Distribution of Ephedrine and Pseudoephedrine Products. The DOJ permits wholesale distributors of all precursor chemicals for meth production, including ephedrine and pseudoephedrine. Under the conditions of a permit a wholesaler must report to the DOJ, all sales and transactions of product, including sales to drug stores. The DOJ reviews the data it receives from these reports, and if anomalies are found, such as a spike in quantity sold, the DOJ will initiate an investigation to determine the cause and source of the anomaly.

4) Based on Oklahoma Law. AB 283 is based on Oklahoma HB 2176 (2004) which went into effect in April 2004. Law enforcement in Oklahoma hope that other states will enact similar provisions.

5) State Legislation. SB 152 (Speier 2005) Pseudoephedrine is similar to AB 283 in its attempt to restrict the sale of pseudoephedrine for illegal uses. SB 152 would require 1) the product be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

6) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

7) History.

2005	
Apr. 13	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
Mar. 14	Referred to Com. on PUB. S.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

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SENATE BILL No. 152

Introduced by Senator Speier

February 7, 2005

An act to add Section 4051.1 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 152, as introduced, Speier. Pseudoephedrine.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy. That law authorizes a pharmacist to furnish and dispense prescription drugs. A knowing violation of the Pharmacy Law is a misdemeanor.

This bill would prohibit, subject to specified exceptions, the furnishing of a product containing pseudoephedrine by other than a pharmacist or pharmacy technician in a pharmacy. The bill would limit the amount of the product that a person could acquire in a 30day period and would impose requirements on acquisition.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4051.1 is added to the Business and Professions Code, to read:

4051.1. (a) A product containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine shall be furnished only by a pharmacist or pharmacy technician in a pharmacy.

(b) Notwithstanding Section 11100 of the Health and Safety Code, no person shall purchase, receive, or otherwise acquire more than nine grams of the product described in subdivision (a) within any 30-day period. Before purchasing, receiving, or otherwise acquiring a product described in subdivision (a), a person shall produce a valid California driver's license or other valid identification containing a photograph of the person and showing his or her date of birth. The person shall sign a written document, as specified by the Attorney General, indicating the date of the purchase, receipt, or acquisition and the amount of the product involved in the transaction.

(c) The pharmacist shall store the product described in subdivision (a) in a locked area within the view of the pharmacist. The pharmacist and all persons with access to the locked storage area shall prevent the theft or diversion of the product.

(d) (1) This section shall not apply to a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. "Active ingredient" includes the matrix found in liquid capsules. Regardless of the product manufacturer's labeling, a gelatin-covered solid is a gel capsule for purposes of this subdivision.

(2) The exception in paragraph (1) shall not apply to a liquid preparation that is discovered in an illegal laboratory, that is associated with an illegal laboratory, or that is any form other than one manufactured and sold by a manufacturer for medicinal purposes.

(e) This section does not apply to a substance furnished pursuant to a valid prescription.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 152 **VERSION: INTRODUCED**

AUTHOR: SPEIER **SPONSOR: SPEIER**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PSEUDOEPHEDRINE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Requires that only a pharmacist or pharmacy technician furnish a product containing any amount of pseudoephedrine, or the salts, isomers, or salts of isomers of pseudoephedrine. (B&P 405.1 Added)

2) Requires a pharmacist to store pseudoephedrine products in a locked area within view of the pharmacist and that the pharmacist and all persons with access to the locked storage area prevent the theft or diversion of pseudoephedrine products. (B&P 405.1 Added)

3) Restricts the purchase of an individual to no more than nine grams of pseudoephedrine in a within any 30 day period. (B&P 405.1 Added)

4) Requires the purchaser of pseudoephedrine products to produce a valid California drivers license, or other valid identification containing a photograph, and for the person to sign a document indicating the date of purchase, receipt, or acquisition of the amount of product involved in the transaction. (B&P 405.1 Added)

5) Exempts from the requirements of the bill a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. (B&P 405.1 Added)

Comment:

1) Author's Intent. The author is seeking to limit the supply of pseudoephedrine available for illegal methamphetamine (meth) production, while making the product reasonably accessible for legitimate use.

2) Enforcement. The board would be charged with enforcing these provisions because the provisions are added to Pharmacy Law. However, enforcement would likely be done by law enforcement who investigate origin of supplies for meth labs. The board would then discipline the pharmacist and pharmacy technician after prosecution by the DOJ.

Moreover the bill does not require that the pharmacy do anything wit the written document for this OTC product that is not regulated by pharmacy provisions requiring 3-year retention.

4) State Legislation. AB 283 (Koretz), Pseudoephedrine: retail sale, is similar to SB 152 in its attempt to restrict the sale of pseudoephedrine for illegal uses. AB 283 would limit access to ephedrine and pseudoephedrine products by requiring 1) the products be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the DOJ. AB 283 would place these provisions in H&SC 11100.01.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

5) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

6) History.

2005	
Apr. 12	Set, second hearing. Hearing canceled at the request of author.
Apr. 11	Set, second hearing. Hearing canceled at the request of author. Set for hearing April 25.
Apr. 4	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 18.
Mar. 23	Set for hearing April 11.
Feb. 24	To Com. on B., P. & E.D.
Feb. 8	From print. May be acted upon on or after March 10.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print

Attachment 7

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AMENDED IN ASSEMBLY MARCH 30, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 446

Introduced by Assembly Member Negrete McLeod
(Principal coauthor: Senator Figueroa)

February 15, 2005

~~An act to amend Section 922 of the Business and Professions Code, relating to medicine.~~ *An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.*

LEGISLATIVE COUNSEL'S DIGEST

AB 446, as amended, Negrete McLeod. ~~Physicians and surgeons~~*Licensees: settlement agreements.*

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct is not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity acting on behalf of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program.

~~Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons. Under existing law, a physician and surgeon whose license has been expired for less than 5 years may be licensed under the Health Care Professional Disaster Response Act if he or she meets specified requirements.~~

~~This bill would also require that the licensee practiced medicine or podiatry for 20 or more years in this state, has reached retirement age under the Social Security Act, and customarily provides free services.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. Section 922 of the Business and Professions Code is amended to read:~~

SECTION 1. Section 143.5 is added to the Business and Professions Code, to read:

143.5. (a) No licensee who is regulated by a board, bureau, or program within the Department of Consumer Affairs, nor an entity acting on behalf of a licensee, shall include or permit to be included a provision in an agreement to settle a civil dispute, whether the agreement is made before or after the commencement of a civil action, that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A provision of that nature is void as against public policy, and any licensee who includes or permits to be included a provision of that nature in a settlement agreement is subject to disciplinary action by the board, bureau, or program.

(b) As used in this section, "board" shall have the same meaning as defined in Section 22, and "licensee" means a person that has been granted a license, as that term is defined in Section 23.7.

~~922. (a) A physician and surgeon who satisfies the requirements of subdivision (d) but whose license has been expired for less than five years may be licensed under this chapter.~~

~~(b) To be licensed under this chapter, a physician and surgeon shall complete an application, on a form prescribed by the Medical Board of California, and submit it to the board, along with the following:~~

~~(1) Documentation that the applicant has completed the continuing education requirements described in Article 10 (commencing with Section 2190) of Chapter 5 for each renewal period during which the applicant was not licensed.~~

~~(2) A complete set of fingerprints as required by Sections 144 and 2082, together with the fee required for processing those fingerprints.~~

~~(c) An applicant shall not be required to pay any licensing, delinquency, or penalty fees for the issuance of a license under this chapter.~~

~~(d) A licensee who has practiced medicine or podiatry for 20 years or more in this state, has reached the age of retirement under the Social Security Act, and customarily provides his or her services free of charge to any person, organization, or agency may be licensed under subdivision (a). If charges are made, the charges shall be nominal, and the aggregate of the charges in any single calendar year shall not be in an amount that would make the licensee ineligible for full social security benefits.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 446 **VERSION: AMENDED MARCH 30, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: NEGRETE MCLEOD**

RECOMMENDED POSITION: SUPPORT

SUBJECT: LICENSEES: SETTLEMENT AGREEMENTS (GAG CLAUSES)

Existing Law:

Permits the board to take enforcement action against a licensee for unprofessional conduct or other violations of the Pharmacy Law.

This Bill:

1) Prohibits a licensee of a board, bureau or program within the Department of Consumer Affairs (DCA) or an entity acting on behalf of a licensee from including a provision in a civil settlement that prohibits the other party from contacting, filing a complaint with, or cooperating with the DCA, or a board, bureau, or program. (B&P 143.5 Added)

2) Prohibits a licensee of a board, bureau, or program within the DCA from including a provision in a settlement for a civil action that requires the other party to withdraw a complaint from the DCA, or a board, bureau, or program. (B&P 143.5 Added)

3) Declares that such provisions (i.e., "gag clauses") to be void as against public policy. (B&P 143.5 Added)

4) Specifies that a licensee who includes or permits a "gag clause" to be included in a settlement agreement is subject to disciplinary action by a board, bureau, or program. (B&P 143.5 Added)

Comment:

1) Author's Intent. According to the author, current law allows licensees to use regulatory gag clauses to keep their misconduct secret and avoid appropriate oversight to the detriment of the public. The full extent to which gag clauses are used by DCA licensees is unknown because they are, by definition, secret.

2) Gag Clauses. This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator. Such an agreement is known as a regulatory "gag clause." A regulatory gag clause requires a plaintiff to agree, as a condition of a malpractice or misconduct settlement with the licensee, to the inclusion of a provision prohibiting the plaintiff from contacting or cooperating with the defendant's regulator (or requiring the plaintiff to withdraw a pending complaint before that regulator.)

As an example, under current law, a physician who settles a malpractice complaint with an injured patient might require, as a condition of receiving the settlement payment, that the consumer not report the malpractice to the Medical Board of California (MBC) or otherwise speak regarding the case, even if the patient is contacted by DCA investigators or private attorneys who are looking into separate complaints against the physician.

3) Attorneys. This bill is modeled on an existing statute that prohibits attorneys from including such clauses in legal malpractice settlements, and is in line with a number of court decisions that describe a compelling public interest in voiding regulatory gag clauses so that the regulator can best protect the public from harm.

4) Previous Legislation. AB 644 is a copy of AB 320 (Correa 2003), which was enrolled and later vetoed by Governor Schwarzenegger. In his veto message the Governor states "under this bill a party who agrees to a civil settlement, could still file a complaint with a regulatory agency subjecting the licensee to double jeopardy. Even after the resolution of a civil suit, this bill could still require a licensee to a second adjudication before a regulatory body."

The board supported AB 320.

5) Amended on March 30, 2005. This bill was gutted and amended on March 30, 2005. The previous version of this bill dealt with physicians and surgeons.

6) History.

2005	
Mar. 31	Re-referred to Com. on B. & P.
Mar. 30	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Feb. 24	Referred to Com. on B. & P.
Feb. 16	From printer. May be heard in committee March 18.
Feb. 15	Read first time. To print.

7) Support and Opposition (for AB 320, 2003)

Support:

State Attorney General's Office
California Architects Board
California Medical Board
California Board of Accountancy
California Board of Optometry
California Board for Professional Engineers and Land Surveyors
Ca. State Board of Pharmacy
Dental Board of California
Board of Vocational Nursing and Psychiatric Technicians
AARP California
American Inst. of Architects Ca. Council
Center for Public Interest Law, University of San Diego Law School
CalPIRG
Citizens Commission on Human Rights
Congress of California Seniors
Consumer Attorneys of California
Consumers for Auto Reliability and Safety
Consumer Federation of California
Consumers Union
The Fund for Animals

Opposition:

Associated General Contractors of California (AGC)
California Building Industry Association (CBIA)
California Business Properties Association
Consulting Engineers and Land Surveyors of California (CELSOC)
Engineering Contractors' Association
California Fence Contractors' Association
Marin Builders' Exchange
California Chapter of the American Fence Contractors' Association

Attachment 8

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AMENDED IN SENATE MARCH 29, 2005

SENATE BILL No. 592

Introduced by Senator Aanestad

February 18, 2005

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as amended, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met. *The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.*

Because a failure to meet the training *and other* requirements in this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the state, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain nondiscretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these nondiscretionary inpatient checking functions, and current rules that require pharmacists to perform these functions unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain nondiscretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

~~SECTION 1.~~

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

~~4128. Notwithstanding any other provision of this chapter or any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. A hospital implementing and operating a program pursuant to this section shall meet all of the following requirements:~~

~~(a) The hospital shall conduct a special training program for technicians who perform the checking function that provides the technicians with the same training that a pharmacist would be provided with under paragraph (1) of subdivision (b) of Section 4052.~~

~~(b) The hospital shall conduct a continuous quality improvement program.~~

~~(c) The hospital shall establish and maintain a program utilizing pharmacists to provide clinical services, as described in Section 4052.~~

~~(d) The hospital shall have a current, nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.~~

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts a special training program for technicians who perform the checking function that satisfies the requirements of subdivision (b).

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is requalified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The training program required by paragraph (1) of subdivision (a) shall include both didactic and practical

elements, and shall specify requirements to be completed prior to the technician commencing participation in the checking program.

(1) The didactic component of the training shall consist of at least four hours of education covering the following topics:

(A) Information required to be on the label of unit dose or extemporaneous packaging.

(B) Identification of expired or contaminated medications.

(C) The product characteristics that need to be checked for each drug dispensed from the pharmacy.

(D) Special packaging or handling requirements, including refrigeration for certain medications.

(E) Generic names for common name-brand medications.

(F) Recognition and identification of various dosage forms.

(G) Common medical abbreviations and symbols used in pharmacy.

(H) Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

(2) The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(c) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section.

(d) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(e) Data and records required by this section shall be retained in each participating hospital for at least three years.

(f) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(g) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be

limited to the holder of the pharmacy permit and the pharmacist in charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certification Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

~~SEC. 2.~~

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: AANESTEAD **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)

2) Requires hospitals implementing TCT to do the following:

a. Conduct ongoing training for technicians.
b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.

e. Be inspected by the Board of Pharmacy.

f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

a. The didactic component of the training shall consist of at least four hours of education covering the following topics:

i. Information required to be on the label of unit dose or extemporaneous packaging.

ii. Identification of expired or contaminated medications.

iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.

iv. Special packaging or handling requirements, including refrigeration for certain medications.

v. Generic names for common name-brand medications.

vi. Recognition and identification of various dosage forms.

vii. Common medical abbreviations and symbols used in pharmacy.

viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT. (B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1Added)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1 Added)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Union (labor), consequently the measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

3) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the January 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in 2006.

4) Amended on March 29, 2005. The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended onJuly 16, 2003.

5) History.

2005	
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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Attachment 9

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ASSEMBLY BILL No. 896

Introduced by Assembly Member Matthews

February 18, 2005

An act to amend Section 4052.1 of, and to add Section 1209.2 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 896, as introduced, Matthews. Clinical laboratories.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under that law, a pharmacist is authorized to perform skin puncture in the course of routine patient assessment procedures or specified clinical laboratory testing. Existing law providing for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services, requires that these functions be performed under the supervision of a laboratory director, as defined. Under existing law, a violation of the provisions regulating clinical laboratories and their personnel is a crime.

This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

Because a pharmacist acting in this capacity without satisfying the designated criteria would violate the provisions regulating clinical laboratories, and would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.2 is added to the Business and Professions Code, to read:

1209.2. Notwithstanding any other provision of law, a pharmacist may serve as a laboratory director, as described in Section 1209, in a clinical laboratory that provides routine patient assessment procedures, as defined in Section 4052.1, if both of the following conditions are satisfied:

(a) The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

(b) The clinical laboratory possesses a certificate of waiver under CLIA.

SEC. 2. Section 4052.1 of the Business and Professions Code is amended to read:

4052.1. *(a)* Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means *either of the following:* ~~(a) procedures~~

(1) Procedures that a patient could, with or without a prescription, perform for himself or herself~~, or (b) clinical~~.

(2) Clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal~~Health Care Financing Administration~~ *Centers for Medicare and Medicaid Services*, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. ~~A~~

(b) A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. ~~Any~~

(c) A pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 896 **VERSION: INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: CPHA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: CLINICAL LABORATORIES

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

4) Defines "routine patient assessment procedures" as a procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived pursuant to CLIA. (B&P 4052.1)

This Bill:

1) Permits a pharmacist to serve as a laboratory director when:

   a. The laboratory is only conducting laboratory tests that a pharmacist may perform under existing law.

   b. The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

   c. The clinical laboratory possesses a certificate of waiver under CLIA.

(B&P 1209.2 Added)

2) The tests that can be preformed are:

   a. Procedures that a patient could, with or without a prescription, perform for himself or herself.

   b. Clinical laboratory tests that are classified as waived under CLIA.

3) Requires the pharmacist performing laboratory tests to report the results to both the patient and any physician specified by the patient. (B&P 4052.1 Amended)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

The author has also introduced AB 1370 this session, which would accomplish the same goal as AB 896. After some reflection, the author has decided to drop AB 1370 and put efforts into AB 896.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available.

Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) Legislative History. AB 896 is similar to AB 1460 (Nation 2003), Laboratory Directors. The board supported this bill. AB 1460 died in its first committee hearing.

6) Related Legislation. AB 1370 (Matthews 2005), Clinical Laboratory Directors: Pharmacists, would amend B&P 1209, to redefine a laboratory director to include a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure. The author's office has stated that the author plans to drop this bill since it would accomplish the same thing as AB 896.

7) History.

2005
Apr. 12 In committee: Hearing postponed by committee.
Mar. 29 In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 7 Referred to Coms. on B. & P. and HEALTH
Feb. 20 From printer. May be heard in committee March 22.
Feb. 18 Read first time. To print.

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Attachment 10

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AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 657

Introduced by Assembly Member Karnette

February 17, 2005

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as amended, Karnette. Pharmacies: prescription containers: labels.

The existing Pharmacy Law provides for the licensing, regulation, and enforcement of the practice of pharmacy by the California State Board of Pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose, *as defined,* of the drug, ~~if~~ *as set forth on the prescription, and would require that* the purpose ~~is~~ *be* listed on the prescription, unless ~~the physician who prescribes the drug or~~ the patient receiving the drug specifically requests that the information be

omitted. By revising the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician

assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

~~(10) The intended purpose of the drug, if the purpose is listed on the prescription, unless the physician who prescribes the drug or the patient receiving the drug specifically requests that the information be omitted.~~

(10) The intended purpose of the drug or drugs, if indicated on the prescription. The prescription shall indicate the purpose of the drug or drugs, unless after consulting with the physician and surgeon, the patient requests that the information be omitted. As used in this section, "purpose" means a concise description of the symptom or symptoms that the drug is, or drugs are, intended to treat.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the

definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 657 **VERSION: AMENDED APRIL 13, 2005**

AUTHOR: KARNETTE **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION:

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled. (B&P 4076(a))

If requested by the patient, a label may list the condition for which the drug was prescribed. (B&P 4076(a)(10))

This Bill:

1) Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription, unless, after counseling with the physician and surgeon, the patient, requests that the information be omitted.

2) Defines "purpose" to mean a concise description of the symptom or symptoms that the drug is, or the drugs are, intended to treat.

(B&P 4076(a)(10) Amended)

Comment:

1) Author's Intent. The author intends to increase patient compliance and reduce confusion with prescribed drug therapy.

2) Confusion. Many prescription drugs have more than one use or purpose. A number of people, particularly seniors, have unexpired prescription drugs in their medicine cabinets, and do not know the intended use for the drug because it is omitted from the label. Many patients are unaware of their right to request that the prescription label contain information about the drug's purpose.

Including the purpose for the prescription drug on the prescription label may 1) reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of a prescription; 2) provide a check system between the doctor writing the prescription and the pharmacist filling the prescription; and 3) reduce medication error.

3) Amended on April 13, 2005. On April 13th, the bill was amended to require a patient to receive counseling from their physician and surgeon prior to requesting the drug's purpose be omitted from drug's prescription label.

The board's legislative committee recommended a position of support on the April 5th version of the bill that would have allowed a patient to request, without counseling from their physician, that the purpose of a drug be omitted from the drug's prescription label.

4) Other Legislation. A version of AB 288 (AB 2125, Levine 2004) was introduced last year. The author pulled the bill before its first committee hearing.

AB 288 (Mountjoy 2005) Pharmacies Prescription Containers Labels, was introduced earlier this year, but has since been dropped by the author.

5) History.

2005	
Apr. 14	Re-referred to Com. on HEALTH.
Apr. 13	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 12	In committee: Set, first hearing. Hearing canceled at the request of author.
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 7	Referred to Coms. on HEALTH and B. & P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

Attachment 11

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AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 225

Introduced by Assembly Member Negrete McLeod

February 3, 2005

An act to amend Section 650 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 225, as amended, Negrete McLeod. Electronic prescription information.

Existing law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions.

This bill would, *upon the effective date of specified regulations adopted by the Secretary of the United States Department of Health and Human Services pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003,* exempt from these provisions ~~a licensed health care facility or licensed health care professional prescribing or dispensing medication~~ *specified entities* that ~~receives~~ *receive* nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, *under certain conditions.*

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 650 of the Business and Professions Code is amended to read:

650. *(a)* Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

~~The~~

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

~~Except~~

(c) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

~~Except~~

(d) (1) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful ~~for a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, as provided in Section 11164 of the Health and Safety Code. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.~~ *to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) in the following situations:*

(A) In the case of a hospital, by the hospital to members of its medical staff.

(B) In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice.

(C) In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

(2) The exceptions set forth in this subdivision are adopted to conform state law with the provisions of Section 1860D-4(e)(6) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) and are limited to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals (42 U.S.C. Sec. 1395w-101).

(3) The exceptions set forth in this subdivision shall not be operative until the regulations required to be adopted by the Secretary of the United States Department of Health and Human Services, pursuant to Section 1860D-4(e) of the Medicare

Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395W-104) are effective.

~~"Health~~

(e) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

~~A~~

(f) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, or by a fine not exceeding fifty thousand dollars ($50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars ($50,000).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 225 **VERSION: AMENDED APRIL 7, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: L.A. CARE HEALTH PLAN**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: ELECTRONIC PRESCRIPTION INFORMATION.

Existing Law:

1) The Federal Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("DIMA") establishing a "safe harbor" for certain health care providers and administrators to exchange "nonmonetary remuneration" under certain limitations to stimulate the use of e-prescribing.

2) State law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions (B&P 650)

This Bill:

1) Allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in the following circumstances:

a. In the case of a hospital, by the hospital to members of its medical staff;

b. In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice; and,

c. In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

2) Limits the application of this bill to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals.

3) Makes this bill operative only when the regulations adopted by the Secretary of the U.S. Department of Health and Human Services become effective.

Comment:

1) Author's Intent. The author's intent is to conform state law to applicable federal provisions so the advances in e-prescribing can take place in California without violating existing state laws. The author believes AB 225 is an initial step towards expanded e-health, and improvements in the quality and efficiency of health care in California, in a fashion consistent with national policies and goals.

2) Consumer Gain? An argument can be made that getting hardware and software for e-prescriptions writing into the hands of prescribers will benefit consumers. Genearally e-prescriptions have been thought of as a way to reduce prescription errors, but recent studies have shown that that while e-prescriptions have reduced errors, they are not error free. Consequently, increasing the number of health care professionals and pharmacies capable of writing and processing e-prescriptions should be in the consumers' interests.

AB 225 may have the unintended consequence of restricting consumer choice. Business and Professions Code section 4170 gives patients the option of obtaining a prescription for a pharmacy of their choice. If prescribers and pharmacies are given hardware and software to facilitate e-prescriptions, a health care professional that has the option of writing e-prescriptions may direct patients to specific pharmacies that have the ability to process these prescriptions with preprogrammed connections to specific pharmacies. These pharmacies may not be the ones a consumer would choose in the absence of the prescriber influence. Additionally, software compatibility (prescribers' and pharmacys') may restrict choice to specific pharmacies again limiting a patient's freedom of choice. Pharmacies that are equipped to process e-prescriptions are likely to see a financial gain if this measure is enacted.

Who stands to gain the most if AB 225 is enacted? Prescribers, consumers, or pharmacies?

3) Amendment. The prescriber, prior to the electronic transmitting of a prescription, offers to transmit the prescription to a pharmacy of the patient's choice.

4) Support & Opposition.

Support:
L.A. Care Health Plan (sponsor)
AARP California
California Association of Health Plans
California Association of Physician Groups
California Medical Association
First 5 LA
Healthcare Information and Management Systems Society, So. Cal
Health-e-LA Coalition
Local Health Plans of California
Los Angeles County Medical Association
Rite-Aid
San Francisco Health Plan

Opposition: None on file.

5) History.

2005

Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 5	In committee: Set, first hearing. Hearing canceled at the request of author.
Feb. 15	Referred to Com. on HEALTH.
Feb. 4	From printer. May be heard in committee March 6.
Feb. 3	Read first time. To print.

Attachment 12

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AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 522

Introduced by Assembly Member Plescia

February 16, 2005

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 522, as amended, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a

mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient *as prescribed by a physician.*

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions which will include all users accessing the system and all drugs added to or removed from the system.

(6) After the pharmacist reviews ~~and approves~~ the prescriber's order, access by licensed personnel to the automated drug delivery system ~~shall be limited only to the prescribed drug authorized by the~~ *shall be limited only to the drug as ordered by the prescriber and reviewed by the* pharmacist and *that is* specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall only

have access to the drug ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 522 **VERSION: AMENDED MACH 29, 2005**

AUTHOR: PLESCIA **SPONSOR: CARDINAL HEALTH**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: AUTOMATED DRUG DELIVERY SYSTEM

Existing Law:

1) Provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. (H&S 1261.6)

2) Regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system. (H&S 1261.6)

This Bill:

Clarifies existing law by:

1. Defining "pharmacy services" as the provision of both routine and emergency drugs and biologicals to meet the needs of the patient.

2. Requiring a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions when an automated drug delivery system is used.

3. Limiting access by licensed personnel to an automated drug delivery system to the prescribed drug authorized by the pharmacist and specific to the patient.

(H&S 1261.6 Amended)

Comment:

1) Author's Intent. The author's intent is to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

2) Legislative History. AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises, expanded the use of automated drug delivery system in skilled nursing facilities. The board supported AB 2184.

3) Proposed Amendment.

Add the words "and dosage" to page 3, line 37 to read:

"After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

4) **Amended on March 29, 2005.** The March 29th amendments were technical and non-substantive.

5) **Support & Opposition.**

Support: Cardinal Health
Amerisource Bergen

Opposition: None on file.

6) **History.**

2005

Apr. 6	From committee: Do pass, and re-refer to Com. on B. & P. with recommendation: To Consent Calendar. Re-referred. (Ayes 11. Noes 0.) (April 5).
Mar. 30	Re-referred to Com. on HEALTH.
Mar. 29	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 28	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

Attachment 13

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AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

SENATE BILL No. 401

Introduced by Senator Ortiz

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or

distributor of prescription drugs, as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that the Legislature finds there is no mandate contained in the bill that will result in costs incurred by a local agency or school district for a new program or higher level of service which require reimbursement pursuant to these constitutional and statutory provisions.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 56.05 of the Civil Code is amended to read:

56.05. For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care

Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) (1) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) "Marketing" does not include any of the following:

(A) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(B) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(C) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or

health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(i) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(ii) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(iii) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free telephone number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(3) "Marketing" includes a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug, that includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any ~~other~~ drug or treatment other than the drug or treatment being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 401 **VERSION: AMENDED APRIL 12, 2005**

AUTHOR: ORTIZ **SPONSOR: CA. PUBLIC INTEREST RESEARCH GROUP**

RECOMMENDED POSITION:

SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING

Existing Law:

1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."

2) Excludes the following from the definition of marketing:

a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.

b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe

c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:

i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.

iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

This Bill:

Defines "marketing" to include a written communication that is provided to a pharmacy patient during a face-to-face interaction with a pharmacist or with pharmacy personnel, in conjunction with the dispensing of a prescription drug if:

1. The communication describes includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any other drug or treatment other than the drug or treatment being dispensed; and
2. The communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

(Civil Code 56.05 Amended)

Comment:

1) Author's Intent. The author's intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition. The author's intent is not to target advertising in patient information leaflets. Consequently, the author is likely to amend the bill to exclude advertising in leaflets from the provisions of the measure.

2) Background. AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party's product or service to a patient, using that patient's medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as "clean-up" legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as "clean-up" legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

3) Previous Legislation.

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

AB 746 (2003) Medical Information: Pharmacies, Marketing; this measure died in the Senate.

4) Support & Opposition

Support: California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Labor Federation Consumers Union

Opposition: California Retailers Association
Catalina Health Resource
Kaiser Permanenente
National Association of Chain Drug Stores
National Council on Patient Information and Education
National Consumers League

5) History.

2005

Apr. 14	Set for hearing April 26.
Apr. 12	Read second time. Amended. Re-referred to Com. on JUD.
Apr. 11	From committee: Do pass as amended, but first amend, and re-refer to Com. on JUD. (Ayes 8. Noes 3. Page 498.)
Apr. 4	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 16	Set for hearing April 6.
Feb. 24	To Coms. on HEALTH and JUD.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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BILL ANALYSIS
SB 401

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

AUTHOR: Ortiz

AMENDED: April 4, 2005
HEARING DATE: April 6, 2005

FISCAL: Judiciary /Appropriations

CONSULTANT: Bohannon / ak

SUBJECT

Medical information: pharmacies: marketing

SUMMARY

The bill would classify a written communication given to a patient by a pharmacist, that includes the name or describes biochemical, pharmacological, or other scientific or health information for any drug or treatment, other than the drug or treatment being dispensed, as marketing, if that communication is paid for or sponsored, directly or indirectly by a manufacturer, labeler, or distributor of prescription drugs.

ABSTRACT

Existing federal law:

1. Establishes the Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services, to regulate the manufacture, labeling, sale, and distribution of drugs in the United States under authority of the Federal Food, Drug, and Cosmetic Act.

2. Requires the Secretary of the United States Department of Health and Human Services to request national organizations representing health care professionals, consumer organizations, the pharmaceutical industry, and various other groups to develop a long-range action plan to achieve goals relating to the provision of oral and written prescription information to consumers.

3.Requires the plan to contain elements necessary to ensure prescription information is scientifically accurate, non-promotional in tone and content, and sufficiently specific and comprehensive as to adequately inform consumers about the use of the product.

4.Establishes the goal of distributing useful written information to 95% of individuals receiving a new prescription by the year 2006.

5.Requires pharmacists to offer counseling to patients who receive benefits under state Medicaid programs.

Existing federal regulations:

1.Requires manufacturers to produce and pharmacists to distribute medication guides (MedGuides) to accompany a limited number of drug products that pose a serious or significant health risk.

2.Requires pharmacies, health plans, and other covered entities to obtain an individual's specific authorization before disclosing their patient information for marketing. Permits doctors and other covered entities to communicate with patients about treatment options and other health-related information.

Existing state law:

1.Establishes the Confidentiality of Medical Information Act (CMIA), which among other things, prohibits any provider of health care, health care service plan, contractor or corporation from intentionally using any medical information, as defined, for any purpose not necessary to provide health care services to the patient, except as expressly authorized by the patient, or as otherwise required or authorized by law.

2.Defines "marketing," for the purposes of CMIA, as making a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

3.Excludes from the definition of marketing the following:

Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration;

Communications made to current enrollees of a health care service plan for purposes related to payment for a product or service, describing plan benefits or services, or describing the availability of more cost effective pharmaceuticals;

Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment in a disease management program, as defined, for a chronic and seriously debilitating or life threatening condition, as defined, if the health care provider receives direct or indirect remuneration, and certain conditions are met. These conditions include requirements that the individual receiving the communication is notified in typeface no smaller than 14-point type that the provider has been remunerated, the source of the remuneration, and allows the individual the opportunity to opt out of receiving future remunerated communications.

This bill:

1. Includes as "marketing", a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug, that includes that name of, or describes biochemical, pharmacological, or other scientific or health information for, any drug or treatment, other than the drug or treatment being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

FISCAL IMPACT

Unknown.

BACKGROUND AND DISCUSSION

Current law requires drug manufacturers to produce and provide to pharmacies, free of charge, a variety of written patient drug safety information, including:

Medicine Guides (MedGuides): The FDA requires pharmacists to distribute MedGuides with a limited number of drug products that pose serious and significant health risks to patients. Medications in this class include the acne drug Accutane, which has been decisively linked to suicide and birth defects. MedGuides are the only form of FDA-approved patient information that pharmacists must distribute with each prescription filled.

Package Inserts (PIs): PIs are part of mandatory labeling for all prescription medications. Although PIs contain

some useful information to patients, they are written for health care providers in great detail using highly technical language.

Patient Package Inserts (PPIs) or Patient Drug Information Leaflets: The FDA requires PPIs for over 150 drugs, not life-threatening enough to warrant a MedGuide, but for which side effects and inappropriate compliance can significantly impact treatment outcomes. For example PPIs are required for oral contraceptives and estrogens. While PPIs are not required to be dispensed with each prescription, they are more often than not included with outpatient prescription medicines dispensed at a pharmacy.

According to the FDA, access to useful patient drug information can facilitate the appropriate use of prescription medicines and avert serious personal injury and increased costs to the health care system. The FDA further suggests that written information about prescription medicines can help patients recognize problem side effects in a timelier manner, expedite treatment, and ensure patients receive the appropriate medications they need to maintain their health. To that end, over the past twenty years the FDA has sought to improve the quality and accessibility of patient drug safety information.

Brief Timeline of Written Medication Information:

1980's

In 1980, the FDA published a final rule establishing requirements and procedures for the preparation and distribution of FDA-approved patient labeling for a large number of prescription drugs (45 FR 60754, September 12, 1980).

The FDA revoked these regulations in 1982 based in part, on assurances by the private sector that the goals of the final rule would be met (47 FR 39147, September 7, 1982). A decision was made to allow voluntary private sector initiatives to proceed before a determination was made whether to impose a mandatory program.

1990's

In 1995, FDA published a proposed rule entitled "Prescription Drug Product Labeling: Medication Guide Requirements" that would have required manufacturers to prepare and distribute "MedGuides" to accompany a limited number of prescription drug products that posed serious or significant public health concern, and set forth requirements for the Medication Guide program (60 FR 44182, August 24, 1995).

The FDA's proposed goal for prescription drugs that did not require MedGuides was that by the year 2000, at least 75% of people receiving new prescriptions would receive useful patient information, and that by 2006, 95% of people who received new prescriptions would also receive such information.

The 1995 proposed rule set criteria by which written information would be judged to determine whether it was "useful" and should therefore count toward accomplishment of the target goals. The FDA defined "useful" as written in non-technical language and containing a summary of the most important information about the drug. The FDA also specified that the usefulness of written patient information would be evaluated according to its scientific accuracy, consistency with a standard format, non-promotional tone and content, specificity, and legibility.

On August 6, 1996, as the FDA was reviewing public comment on the 1995 proposed rule, Public Law 104-108 was enacted and mandated that the private sector be given the opportunity to meet the distribution and quality goals proposed by the rulemaking on a voluntary basis.

The law also directed the Secretary to facilitate the development of a long-range comprehensive action plan in coordination with national organizations representing health care professionals, consumer organizations, the pharmaceutical industry, and others. Additionally, the law required the Department of Health and Human Services to review the status of the private sector initiatives designed to achieve the goals of the action plan by January 1, 2001.

2000's

In 2001, the FDA commissioned the National Association of Boards of Pharmacy to subcontract a national study to assess the "usefulness" of written prescription drug information being distributed to patients. The results of the study were announced in 2002 and found that on average, 89% of patients received some form of written medication information. However, the study found that the average "usefulness" of the information was only about 50%.

In 2003, stakeholders participated in meetings at the Keystone Center and developed an action plan for implementing the law's objectives for 2006.

Direct-to-Consumer Advertising

According to the author, some pharmacists' written communications additionally include direct-to-patient (DTP) or point-of-care (POC) advertisements, types of direct-to-consumer (DTC advertising) that are sponsored by drug manufacturers that promote competing drugs and treatment therapies. According to the Kaiser Family Foundation, promotional spending by pharmaceutical manufacturers has risen steadily in recent years, more than doubling from $9.2 billion in 1996 to $19.1 billion in 2001, an average annual increase of 16%. While most promotional spending (86%) remains directed at physicians, a growing proportion is directed at consumers. According to information obtained from Catalina Health Resource, opponents of the bill, POC advertising can lead to an average incremental volume lift of more than 8% for some prescription medications with an average return on investment of over 3 to 1.

However, previous research by the FDA and other entities has also documented that accurate DTC advertising can lead to significant increases in the detection of undertreated conditions like high blood pressure, diabetes, and depression. FDA surveys in 1999 and 2002 showed that DTC advertising encouraged substantial numbers of patients to ask their doctors about a medical condition or illness of their own that they had not talked to a doctor about before. The surveys also showed that DTC advertising encouraged patients to obtain more health information from a physician or pharmacist.

Arguments in support

Supporters of the bill, assert that pharmacists are regarded as the most trusted health care professional and contend that such communications could be mistaken as a tacit endorsement of a particular drug or an implicit veto of a physician's recommended course of treatment.

Supporters of the bill insist that patients have a reasonable expectation that the information they receive from the pharmacy is objective. They insist that inserting paid advertising into the pharmacist/patient interaction betrays that expectation and changes the role of the pharmacist from unbiased information provider to drug company salesperson. They assert that this kind of advertising can undermine consumer confidence in the essential scientific information about dosage, side effects, and potential drug interactions that patients do need to receive from their pharmacists.

Supporters of the bill also believe that since this advertising may conflict with a doctor or pharmacists instructions for other prescriptions, it can also create a great deal of confusion for elderly patients, the chronically ill, or those with a large number of prescriptions. Supporters also assert that drug safety concerns call for increased caution in expanding prescription drug marketing. They cite the recent highly publicized recall of the popular painkiller Vioxx, which they insist affected far more consumers than it should have due to aggressive DTC advertising.

Arguments in opposition
Opponents of the bill believe that SB 401 will interfere with the distribution of valuable information to the detriment of patients. They believe consumers should receive as much information as possible about their conditions, their prescription drugs and treatment alternatives, including compliance and persistence messaging, disease state management materials, and information about alternative or adjunctive therapies.

They assert that pharmaceutical manufacturers often underwrite the costs of many of these written in-pharmacy communications, which pharmacists are obligated to provide under federal law. They insist that obtaining sponsors for these communications is an attractive option for pharmacies that would otherwise have to bear the entire cost of these informational materials. They believe that in considering legislative restrictions on patient messaging, the focus should be on the value of the content and not on whether some part of the message has been sponsored.

Opponents additionally assert that pharmacies have experienced significant cuts in their reimbursement rates from the state's Medicaid program, workers' compensation and private payers, while paying increasingly more for prescription drugs. They believe SB 401 represents another operating cost that would have to be shouldered by pharmacies whose margins are already tightly constrained.

Opponents also insist that SB 401 is contrary to federal Health Insurance Portability and Accountability Act privacy regulations which determined that refill reminders and information about treatment options and alternatives should be considered as part of the patient's treatment, which the patient is considered to have agreed to by filling the original prescription.

Prior / Relevant legislation
AB 95 (Koretz, 2005) requires drug manufacturers to

provide a rebate to the state for drug marketing costs related to drugs for life-threatening conditions purchased by the Medi-Cal and AIDS Drug Assistance programs. Contains an exemption for legitimate physician education costs. This measure is currently in the Assembly Health Committee to be heard on April 12, 2005.

SJR 24 (Ortiz, Chapter 139, Statutes of 2004) memorializes the President and Congress to recognize the problems caused by DTC advertising of prescription drugs and to take specified actions to remedy its negative effects.

AB 746 (Matthews, 2004) would have established specified exemptions for in-pharmacy marketing communications. This measure died on the Senate Floor.

AB 715 (Chan, Chapter 562, Statutes of 2003) prohibits a health care provider, health care service plan, contractor, or corporation from using patients' private medical information for marketing purposes where the use is not necessary to provide health care services without the patient's express authorization, with certain exemptions.

POSITIONS

Support: California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Labor Federation
Consumers Union

Oppose: California Retailers Association
Catalina Health Resource
Kaiser Permanenente (unless amended)
National Association of Chain Drug Stores
National Council on Patient Information and Education
National Consumers League